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Datasheet for the decision of 3 November 2015

Case Number: T 1683/11 - 3.2.02

Application Number: 07001829.6

Publication Number: 1790304

IPC: A61B18/14, A61M25/10, A61M25/09

Language of the proceedings: EN

Title of invention:
Tissue ablation system including a balloon anchor wire

Applicant:
Atrionix, Inc.

Headword:

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
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Case Number: T 1683/11 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 3 November 2015

Appellant: (Applicant)	Atrionix, Inc. 1820 Embarcadero Road Palo Alto CA 95130 (US)
Representative:	Brunner, John Michael Owen Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 16 February 2011 refusing European patent application No. 07001829.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	P. L. P. Weber
	C. Körber

Summary of Facts and Submissions

I. The appeal of the applicant is against the decision of the Examining Division posted on 16 February 2011 to refuse the application for lack of novelty and/or inventive step. The decision under appeal is a so-called decision according to the state of the file referring to a communication dated 23 March 2010. The subject-matter of claim 1 was considered to lack novelty over D1: WO-A-98/49957.

II. The notice of appeal was filed by fax on 20 April 2011 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed by fax on 27 June 2011.

III. Oral proceedings were held on 3 November 2015.

The final request of the appellant was the following:

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, in the alternative, one of the first to the third auxiliary requests, all filed with letter dated 27 June 2011.

IV. The documents of importance in the present decision are the following:

D1: WO-A-98/49957
D3: US-A-5207229
D4: US-A-5167239

V. The application on which the decision is based is a divisional application of EP-A-1179995.

The descriptions, claims and drawings of the divisional application and of the parent application as filed are identical. In the following, the Board will refer to the description of the divisional application because of the paragraph numbering.

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

"A tissue ablation system for ablating a region of tissue at a location where a pulmonary vein extends from an atrium in a patient, comprising:

an anchor device having an elongate body (12) with a proximal end portion and a distal end portion that is adapted to be positioned within the pulmonary vein, and also having an expandable member (14) along the distal end portion adjustable between a radially collapsed condition and a radially expanded condition that is adapted to engage the pulmonary vein; and

an ablation device comprising an elongate catheter (80) having a proximal region and a distal region (84), and an ablation element (88) located along the distal region, wherein the ablation device is adapted to slideably engage and track over the elongate body (12) of the anchor device, such that the ablation element can be ablatively coupled to the region of tissue by advancing the ablation device distally over the elongate body of the anchor device towards the expandable member (14)."

Claims 2 to 19 are dependent claims.

VII. The main arguments of the appellant, relevant for the decision, are essentially those on which the following reasons for this decision are based.

Reasons for the Decision

1. The appeal is admissible. The statement setting out the grounds of appeal was filed in due time, since 26 June 2011 was a Sunday.

2. Invention

In order to stop atrial fibrillation, it is known to create linear lesions close to the pulmonary vein ostia in the left atrium. This can be done with catheter assemblies having ablation means guided to the desired location and maintained there long enough to create the lesions. The invention concerns such a catheter and anchor device. A system comprising an anchor device according to the invention is suitable to be guided into the pulmonary vein and anchored there with an expandable member. The ablation device is adapted to be moved over the elongate body of the anchor device until it reaches the place for ablation.

3. Novelty

3.1 Novelty over D1

The ablation system disclosed in D1 can best be understood from Figures 3 to 6 and the corresponding passages of the description. Two guidewires 3 and 4 are introduced into two of the pulmonary veins and positioned therein. The ablation catheter is then guided over these guidewires to be brought into the position for ablation, as can be seen in the mentioned figures and as is explained on page 20, lines 14 to 22. In this document the guidewires and the guidewire

tracking members 30, 40 are considered to be the anchoring elements of the ablation element 20 of the ablation device. The guidewires are placed first, then the ablation element is guided over the guidewires until the distal end of the ablation element abuts the stop means 13 on the first guidewire 3. By further pushing the catheter (including the ablation element), it will further move along the second guidewire 4, such that the ablation element 20 is brought into contact with the tissue to be treated. According to the embodiment of Figure 6, an expandable member 35 on the ablation element may secure it in the vein (page 24, line 31 to page 25, line 11).
On page 15, lines 15 to 21, the following can be read in relation to the first embodiment: "*The stop (13) provides one positioning means for placing the distal guidewire tracking member (30) at a predetermined location along the guidewire to anchor it in that position in the anatomy, as will be more readily apparent by reference to Figure 3 below. In addition to the use of the stop mechanism shown, other structures may be employed to provide relative positioning of the catheter over the guidewire, such as by use of an expandable member on the guidewire to internally engage the guidewire tracking lumen, as would be apparent to one of ordinary skill.*"

The appellant considered that the guidewire according to D1 could not be considered to be an anchor device as required by claim 1, because it was clear for the person skilled in the art reading the application as filed that in the context of the invention the anchor device had to be "anchorable" or fixable in the pulmonary vein close to the atrium of the patient in order for the desired ablation operation to be performed.

The Board does not share this opinion. The wording of claim 1 does not specify in general terms where the anchor device has to be anchored. It only requires the anchor device to be adapted to be positioned within the pulmonary vein, and to have an expandable member along the distal end portion. The same is true for the guidewire disclosed in Figure 3 of D1, since it is positioned in the pulmonary vein and (can be) anchored inside the guidewire tracking lumen with an expandable member. The anchor device of claim 1 as such is therefore anticipated by the guidewire of the embodiment shown in Figure 3 of D1.

The Examining Division considered that the guidewire was the anchor device of claim 1 and that it was provided with an expandable member (as mentioned in the above paragraph). According to the Examining Division, this expandable member would also be suitable for engaging the pulmonary vein in its radially expanded condition, as required by claim 1. Hence, since the other features were also disclosed, the Examining Division considered that D1 was novelty-destroying.

The Board cannot follow the opinion of the Examining Division for the following reasons:

There is no teaching in D1 to physically anchor the guidewire in the pulmonary vein. This is not addressed in D1 at all. The above-mentioned paragraph on page 15 is about an expandable member which engages the guidewire tracking lumen, not the pulmonary vein. The guidewire tracking lumen clearly is not as big as the vein into which the whole catheter is meant to be introduced. The question to be answered in relation to novelty is therefore whether this expandable member on

the guidewire is suitable, either explicitly or implicitly, to radially expand to a sufficient extent as to engage the pulmonary vein.

Considering the embodiment of Figure 3, it seems unrealistic to believe that the guidewire could be introduced into a part of the pulmonary vein which would be so small that the expandable member meant for the guidewire tracking lumen would be able to engage its walls, because the guidewire disclosed in Figure 3 of D1 is provided with a stop means 13 in the shape of a ball having a diameter substantially bigger than a guidewire tracking lumen, so that this stop means would not be able to penetrate the said smaller part of the vein.

D1 also fails to explicitly disclose that the expandable member on the guidewire would be able to expand to a size equivalent to or bigger than the diameter of the pulmonary vein at a location close to the atrium where the ablation catheter will be placed. Neither can it be considered to implicitly disclose such a feature, because there is no information whatsoever in D1 pointing to such a capability. For instance, there is no information as to how the expandable member is constructed, the materials used for it, etc.

It follows that there is no directly and unambiguously derivable information in D1 that the expandable member of the guidewire shown in Figure 3 can be considered to be suitable to be in a radially expanded condition that is adapted to engage the pulmonary vein, as required by claim 1.

Hence, the subject-matter of claim 1 is novel over D1.

3.2 None of the other documents cited in the search report anticipates the subject-matter of claim 1. The cited E-document is not a prior right, since it has the same priority date (and the same filing date) as the present application and the priority of the present application is valid.

3.3 Hence, the requirements of Article 54 EPC are fulfilled.

4. Inventive step

From the documents cited in the examining phase, D1 is the most promising. The Board further considers that the embodiment shown in Figure 6 is the closest prior art because it has fewer differences over the claimed subject-matter than the embodiment according to Figure 3. As already mentioned in relation to novelty, in the embodiment according to Figure 6, an expandable element 35, e.g. an inflatable balloon (page 25, line 8), is present on the ablation element which will help to position and secure the ablation element in the pulmonary vein (page 24, line 31 to page 25, line 2: "*Figure 6 show still a further variation of the ablation element anchoring feature of the current invention, wherein the distal end (23) of ablation element (20) is bordered by an expandable element (35) which is adapted to radially engage at least two opposite portions of the pulmonary vein wall within which the expandable element is positioned.*").

Hence, starting from the embodiment according to Figure 6 of D1, the differentiating feature is the following:

(i) the radially expandable member that is adapted to engage the pulmonary vein is on the ablation element 20 in D1 and not on the guidewire (or anchor device), as required by claim 1.

While having the expandable member on the ablation element allows a precise and secure positioning of the ablation element relative to the pulmonary vein, placing the expandable member on the guidewire 3 in the embodiment according to Figure 6 would have the effect of fixing or securing the guidewire, instead of the ablation element, relative to the pulmonary vein, which in turn would facilitate a change of position of the ablation element without the risk of displacement of the latter or of getting out of the pulmonary vein. Indeed, changing the axial position of the ablation element shown in Figure 6 would require the "deflation" of the inflatable balloon 35 and reexpansion thereof at the desired place.

The objective problem solved by the claimed invention can thus be seen as one of facilitating the positioning and repositioning of the ablation element in situ.

There appears to be no suggestion in the cited prior art to transfer anchoring elements, including a radially expandable member able to engage the wall of the pulmonary vein, from the ablation device or element to a separate anchoring device or to a guidewire. The person skilled in the art faced with the above problem would, on the contrary, find an alternative solution in D1, for instance, in the embodiment according to Figures 3 or 5, in which the idea is to position the guidewires in the pulmonary veins and to hold or block them there from outside the body of the patient, the first guidewire additionally having a stop means 13

(the second one possibly as well, Figure 4 element 14) against which the ablation element abuts to be precisely positioned, and possibly having, on the guidewire, an expandable member inside the guidewire tracking lumen which helps maintain the ablation element in a fixed position relative to the guidewire. Quite obviously, in this embodiment it is easier to adjust the position of the ablation element, if desired, because it is not secured against the wall of the pulmonary vein.

Hence, in the opinion of the Board, if anything, if a more flexible positioning of the ablation element on the guidewire is desired, D1 teaches to block the guidewires from outside the patient body and to put an expandable member onto the guidewire, whereby the expandable member is inside the guidewire tracking lumen so as to be able to secure the ablation element relative to the guidewire.

Of course, guidewires with balloons (e.g. D3) or anchoring balloons (e.g. D4) are known, but not only is there no teaching in these documents that such a feature would be interesting for positioning a catheter precisely relative to a body part, but there is also no information in these documents as to any possible advantage that might be afforded by such an expandable member in combination with an ablation device for ablating a region of tissue at a location where a pulmonary vein extends from an atrium in a patient. It follows that the Board does not even see a reason why the person skilled in the art would consult these documents.

Hence, the requirements of Article 56 EPC are fulfilled.

5. The description has been adapted.

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 19 of the main request, filed with letter dated 27 June 2011;
   - Adapted description pages 1 to 36, filed on 3 November 2015;
   - Figures 1A to 11 of the original application.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated