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D E C I S I O N
of 5 December 2001

Case Number: T 1017/00 - 3.2.2

Application Number: 96941423.4

Publication Number: 0865256

IPC: A61B 17/39

Language of the proceedings: EN

Title of invention:
Systems and methods for electrosurgical myocardial revascularization

Applicant:
ARTHROCARE CORPORATION

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 52(1), 54, 56, 123(2)

Keyword:
"Essential features omitted from claim 1 - no"
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 1017/00 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 5 December 2001

Appellant: ARTHROCARE CORPORATION
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 26 May 2000 refusing European patent application No. 96 941 423.4 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: S. S. Chowdhury
R. T. Menapace

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 26 May 2000 to refuse European patent application No. 96 941 423.4 on the ground that the claims of the main and auxiliary requests did not meet the requirement of Article 123(2) EPC.

The grounds of refusal were that features that were defined in claim 34 of the application as originally filed were omitted from new claim 1 which was based on that claim, and that dependent claim 19 included an added feature.

II. On 25 July 2000 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee. A statement of grounds of appeal was filed on 4 October 2000.

III. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the following documents:

- Claims 1 to 24 filed by telefax on 6 November 2001

- Description pages 1 to 46 filed by telefax on 30 November 2001

- Original drawing sheets 1/21 to 21/21.

IV. Claim 1 reads as follows:

"An electrosurgical device for myocardial revascularization of a patient's heart tissue, the device comprising: a catheter shaft (206) configured

for endoluminal delivery into the patient's ventricular cavity and having proximal and distal end portions and an electrode terminal (58) disposed on the distal end portion; a return electrode (56); and a high frequency power supply (28) for applying a voltage difference between the return electrode and the electrode terminal, the voltage difference and the resulting current being sufficient to vaporise electrically conductive liquid and to cause ionization within the vapour layer to effect volumetric removal of heart tissue adjacent to the electrode terminal."

V. The examining division based its decision to refuse the application on the following arguments:

Claim 1 omitted the following features of claim 34 [highlighted in bold type by the Board] of the application as originally filed:

a) The return electrode is **disposed on the shaft**

b) A **connector** is provided for coupling the **active and return electrodes** to a high frequency voltage source.

The omission of the location of the return electrode on the catheter shaft was not justified since, although the application comprised 46 pages of description, the applicant relied on only two sentences to support this omission, one of which was not relevant and the other of which provided no valid support for the omission. While new claim 1 was based on the volumetric removal of material that required high voltages, the application was originally drafted to include various electrosurgical devices in general including those that

did not provide for volumetric removal of tissue.

No passage of the description as originally filed referred to volumetric removal of tissue and also clearly disclosed an electrode other than on the catheter shaft. Also none of the figures showed such a device. This was not surprising since volumetric removal of tissue required there to be a discrete distance between the electrodes for an arc discharge to be ignited, which would not appear possible if the return electrode were placed elsewhere.

Original method claim 1 could not be regarded as a valid basis for the claim broadening either since the claim referred to electrosurgical procedures in general including those where only coagulation might be the aim, whereas the device claim then under consideration referred to the particular embodiment of volumetric removal of tissue. A return electrode on the catheter shaft was an essential feature, accordingly.

Original claim 34 comprised the sole basis for claim 1 and it explicitly defined the return electrode to be on the catheter shaft. Thus, the claim was inadmissibly broadened and did not meet the requirement of Article 123(2) EPC.

The feature that the electrically conductive fluid comprises blood or other fluids existing within the heart wall had been added to claim 19.

VI. During the examination procedure the examining division had cited the following documents as being relevant for the examination as to the requirements of Article 52(1) EPC:

D1: US-A-5 083 565

D2: US-A-5 098 431

VII. The appellant argued as follows:

There was explicit basis on pages 10, 20, and 31 of the application for the added feature in claim 19.

The application as originally filed stated explicitly that the return electrode may be on a separate instrument, and it also contained claims and statements of invention which were not limited to any particular placement of the return electrode or the use of a connector. Nothing in the application suggested that the position of the return electrode or the means for connecting the return electrode were in any way essential to the invention. The application as a whole left open the question of how a return electrode on a separate instrument was to be connected, this being a simple and unimportant matter for the person skilled in the art. An affidavit from a person skilled in the art confirmed these arguments.

Reasons for the Decision

1. The appeal is admissible.

2. *Background to the present invention*

2.1 The opening paragraphs of the application describe prior art laser myocardial revascularization (LMR) devices and their drawbacks, and under "Description of the Background Art" on page 4 there is cited prior art

that describes LMR devices as well as devices incorporating radio frequency electrodes for use in electrosurgical and electrocautery techniques. Both monopolar and bipolar electrosurgical devices are described. The present invention is concerned with an alternative to the above LMR procedures that are said to have disadvantages.

2.2 Monopolar electrosurgical devices are those in which an active electrode is placed on a probe and a return electrode is placed in contact with the patient, and bipolar devices are those in which two electrodes are provided in close proximity to each other on a probe and no patient return electrode is necessary.

2.3 Two different surgical approaches may be employed for myocardial revascularization, whereby the active electrode on the probe may be introduced to the heart, respectively, (i) via the thoracic cavity or (ii) by endoluminal delivery. In approach (i), called the pericardial approach, the probe is delivered directly through a median thoracotomy or through an intercostal percutaneous penetration, such as by a cannula or trocar sleeve in the chest wall between two adjacent ribs, and the electrode creates a channel from the epicardium into the myocardium by ablation and volumetric removal of tissue. In approach (ii), called the endocardial or intra luminal approach, the probe is introduced through a percutaneous penetration in the patient and axially translated through one of the major arterial vessels to the left ventricular cavity, and the electrode creates a channel from the endocardium into the myocardium, also by ablation of tissue.

The presently claimed invention is limited to devices

configured for endoluminal delivery into the patient's ventricular cavity, ie approach (ii) type devices.

3 *The main objection*

3.1 It is the main contention of the examining division that original claim 34, on which new claim 1 is based, was restricted to bipolar devices and that the application as originally filed did not disclose monopolar electrosurgical probes for endoluminal delivery, and that the applicant was now attempting, by way of deletion of features from the claim, to include monopolar devices within the scope of claim 1, which is not justified.

3.2 The criterion for allowing the deletion of this feature from the claim boils down to whether the application as originally filed is understood to disclose a return electrode **on the shaft** as an essential feature. The question must be answered from the point of view of the person skilled in the art reading the application as a whole.

4 *The disclosure of the application as originally filed*

4.1 The present invention relates to surgical devices that employ high frequency energy to cut and ablate heart tissue for increasing the flow of blood to a patient's heart (see the first paragraph on page 1 and page 5, lines 11 to 21), and original claims 1 and 34 related to ablation devices accordingly, which work by the volumetric removal of tissue (see page 5, lines 27 to 30). Thus, the invention as claimed was and still is concerned exclusively with the volumetric removal of tissue, and the examining division's argument, that the

application as originally filed was drafted to include various electrosurgical devices in general including those that did not provide for volumetric removal of tissue, is wrong.

4.2 The present application is an International Application, whose layout is governed by the PCT. The heading "Summary of the Invention" in such applications defines the invention in its broadest aspect, and this section is followed by a description of specific features and examples of the invention. The passages under "Summary of the Invention" on page 5 of the present application, immediately following "Description of the Background Art", present the invention as a further development of the prior art (which includes both monopolar and bipolar electrosurgical devices) and do not exclude monopolar devices either explicitly or by implication.

The first paragraph under this heading on page 5 says "The present invention allows the surgical team to perform electrosurgical interventions, such as ablation and cutting of body structures......." and "The systems, apparatus and methods of the present invention are particularly useful for canalizing or boring channels or holes through tissue, such as the ventricular wall of the heart during transmyocardial revascularization procedures". The second paragraph describes the method whereby the active electrode may be introduced to the heart via both the approaches, (i) or (ii), and the third paragraph, starting on page 6, line 3 states the advantages of the invention. Each of these three paragraphs can be read onto both monopolar and bipolar device, and in none of these paragraphs is the position of the return electrodes given any

importance.

There then follows a paragraph describing a device for intercostal delivery, with the first references to the return electrode, which may be integral with the probe or provided on another instrument. This is followed by a paragraph in which ventricular application is discussed, but there is no mention of the return electrode here. Neither here nor anywhere else in the application is its position given any importance. The inference is that this is done in the conventional manner, ie either a monopolar or a bipolar device may be used.

4.3 Further embodiments are described on page 9, lines 10 to 23, in which both types of surgical approaches are described and, with respect to one embodiment, it is stated that "The return electrode may be provided integral with the shaft, **or it may be separate** from the shaft" [emphasis added] in connection with intra luminal delivery. This is, therefore, explicit support for the broadened claim.

4.4 In the various descriptions of the invention and its embodiments in the above passages, whereas the position of the active electrodes is consistently stated to be on the catheter shaft, this contrasts with the position of the return electrode, which is specified as being either integral with the probe, or on another instrument in the approach (i) devices (page 6, line 26 to page 7, line 12), or the position is left open in devices using surgical approach (ii) (page 7, lines 13 to 30).

4.5 The argument of the examining division, that no passage

of the description as originally filed referred to volumetric removal of tissue and clearly disclosed an electrode other than on the shaft, is clearly wrong as shown above. The examining division's argument that the applicant relied on only two sentences for support for the omission of a feature from original claim 1 is not valid since the suitability of a disclosure for supporting a feature in the claims is not dependent on the length of the text of the disclosure.

4.6 Moreover, original claim 1 defines an invention which is a method of revascularizing a portion of a patient's myocardium, comprising positioning an active electrode on a wall of the patient's heart and applying high frequency voltage between the active electrode surface and a return electrode to ablate tissue at the heart wall and to form a revascularizing channel through at least a portion of the heart wall. This claim does not specify the position of the return electrode and clearly covers both types of electrosurgical probes that were originally disclosed. Therefore, the examining division's argument, that original method claim 1 could not be regarded as a valid basis for claim 1 according to the main request since the original claim referred to electrosurgical procedures in general including those where only coagulation might be the aim, is not valid.

This argument is also wrong for the reason that coagulation is, in fact, to be avoided in the practice of the present invention, see the paragraph linking pages 25 and 26.

4.7 Therefore, it is clear that, while all the specific embodiments of the application described with reference

to the drawing describe bipolar devices, and original claim 34 was also restricted to such a device, the application as originally filed and taken as a whole, did envisage an invention comprising an electrosurgical device for myocardial revascularization of a patient's heart tissue, configured for endoluminal delivery into the patient's ventricular cavity, and which is a monopolar device. Thus, the omission of the position of the return electrode from claim 1 is supported by the application as originally filed, and no objection to it arises under Article 123(2) EPC.

4.8 Omission of the connector

The omission of this feature from claim 1 is linked with the omission of the feature relating to the position of the return electrode. The description makes only sparse references to the connector, and in this respect too the question is how would the person skilled in the art read the application?

The Board accepts the argument in the Affidavit of Dr Woloszko dated 7 April 2000, that since nothing in the application states that the return electrode in a monopolar device should be connected in a particular way, it would be assumed that a conventional arrangement would be used, in which the return electrode has its own connector. It would be unreasonable and unorthodox, in a monopolar device, to connect a return electrode, for example in the form of a contact pad, via a connector on the catheter shaft.

In other words, once it is accepted that the application as originally filed did disclose monopolar electrosurgical probes for endoluminal delivery, then

it must also be conceded that a connector on the shaft is not indispensable and that this need not feature in claim 1 as an essential element.

4.9 Reference to other fluids

The feature in claim 19 that the electrically conductive fluid comprises blood or other fluids existing within the heart wall is adequately supported by the application as originally filed on page 10, lines 19 to 22, page 20, last paragraph, and page 31, lines 3 to 11, so that no objection to the claim arises under Article 123(2) EPC.

4.10 Other amendments

The dependent claims correspond to some of the dependent claims originally filed and the description has been revised for consistency with the new claims and to include a reference to relevant prior art under Rule 27(1)(b) EPC.

5. *Article 52(1) EPC*

5.1. The examining division, in its first communication dated 31 May 1999, set out its objections under Article 123(2) EPC, that were later to form the basis for the refusal of the application and which have been dealt with above, and requested the applicant to meet some formal objections, including making a reference in the description to the document D1 and casting the claims in the correct two-part form having regard to this document. The implication was that the position under Article 52(1) EPC was satisfactory and that grant of a patent was envisaged pending correction of the

formal defects. It was only just before the oral proceedings before the examining division that a new document, D2, was cited as novelty destroying for all requests.

5.2 As regards document D1, the Board agrees with the examining division that this document does not endanger the claimed apparatus. The document describes an apparatus configured for endoluminal delivery for ablating ectopic foci. The apparatus would not be capable of performing myocardial revascularization of a patient's heart tissue by causing ionization within a vapour layer to effect volumetric removal of heart tissue, because it comprises a probe that has two distal end electrodes that can be extended from a retracted position to pierce the myocardium, whereafter an RF current ablates the tissue between the electrodes so as to destroy the tissue locally. There is no volumetric removal of tissue such as to enable the probe to advance and perform myocardial revascularization.

5.3 The document D2 is prima facie not relevant and the Board makes use of its power conferred by Article 111(1) EPC to examine this document and compare it with the claimed invention. This document discloses an intravascular RF ablation catheter for the surgical removal of atheromas or other lesions from the interior walls of blood vessels. An annular arc is struck between the distal electrodes of a probe, the arc extending circumferentially about the probe so as to remove deposits on the walls of a blood vessel. This device is not intended for, indeed it is not suitable for, performing myocardial revascularization of a patient's heart because of an insulating distal end

layer that would prevent an RF current from flowing in the longitudinal direction and causing volumetric removal of tissue such as to perform myocardial revascularization.

5.4 Previously, laser myocardial revascularization (LMR) had been used in the endocardial approach in which an optical fibre is introduced through a percutaneous penetration into the heart and the laser radiation creates a channel from the endocardium into the myocardium (for example US-A-5 389 096 mentioned in the description). Page 3 of the application reviews the drawbacks associated with LMR devices, which are that the channels formed are very small in diameter and may close again rapidly, it is difficult to control the location and depth of the channels, the extent of penetration of the laser beam into the tissue is difficult to control, etc.

5.5 It was to overcome these drawbacks that the present electrosurgical device was developed. No prior art document describes the above problems with LMR devices or an electrosurgical device configured for endoluminal delivery for performing myocardial revascularization of a patient's heart tissue by causing ionization within a vapour layer to effect volumetric removal of heart tissue. Whereas myocardial revascularization from the epicardium into the myocardium using an electrosurgical device was known, it was not known to use an electrosurgical device to perform this operation from the endocardium into the myocardium. Consequently, the prior art does not disclose or suggest the presently claimed electrosurgical device configured for endoluminal delivery.

Therefore, the Board concurs with the examining division, that the position under Article 52(1) EPC, before document D2 was cited, was satisfactory. Moreover, as stated above, the latter document is also not relevant to the present invention.

6. All formal objections raised by the first instance have also been overcome by the amended application, so that it is now in order for grant.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to grant a patent on the basis of the documents set out in point III above.

The Registrar: The Chairman:

V. Commare W. D. Weiß