Datasheet for the decision of 20 March 2009

Case Number: T 1296/07 - 3.2.02
Application Number: 03079207.1
Publication Number: 1415607
IPC: A61B 18/14
Language of the proceedings: EN
Title of invention: A moisture transport system for contact electrocoagulation
Applicant: Novacept
Opponent: -
Headword: -
Relevant legal provisions: EPC Art. 52(1), 56
Relevant legal provisions (EPC 1973): -
Keyword: "Inventive step (yes, after amendment)"
Decisions cited: -
Catchword: -
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DECISION
of the Technical Board of Appeal 3.2.02
of 20 March 2009

Appellant: Novacept
1047 Elwell Court
Palo Alto
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Representative: Jackson, David Spence
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Decision under appeal: Decision of the Examining Division of the European Patent Office posted 18 December 2006 refusing European application No. 03079207.1 pursuant to Article 97(1) EPC.

Composition of the Board:
Chairman: M. Noël
Members: S. Chowdhury
         M. J. Vogel
Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 18 December 2006 to refuse European patent application No. 03 079 207.1.

The application was refused on the grounds that the subject-matter of claims 1 to 18 then on file lacked an inventive step having regard to:

D2: US-A-5 451 204 and

II. On 14 February 2007 the appellant lodged an appeal against the decision and paid the prescribed fee on the following day. On 17 April 2007 a statement of grounds of appeal was filed.

The appellant requests that the decision be set aside and a patent be granted on the basis of the claims 1 to 13 filed on 3 March 2009.

III. Independent claim 1 reads as follows:

"An ablation apparatus for use in delivering energy to tissue for ablation, the apparatus comprising: an electrode carrying member (12); a bipolar array of electrodes (14) on the electrode carrying member (12); a source (42) of radio frequency energy coupled to the electrodes; and structural support means (15, 19; 52) within the electrode carrying member (12) for holding the electrode carrying member in an open condition, the electrode carrying member (12) being moisture permeable
and coupled to a suction means (40, 17) arranged to apply suction to the interior of the electrode carrying member (12) when the electrode carrying member is in the open condition and, during ablation using the electrodes, operable to draw moisture released by tissue undergoing ablation through the electrode carrying member (12) and into the suction means (40, 17) to substantially prevent formation of a low impedance liquid layer around the electrodes when ablation is carried out using the electrodes (14) whereby ablation is self terminating.”

Claims 2 to 13 are dependent claims.

Reasons for the Decision

1. The appeal is admissible.

2. Amendments

2.1 Claim 1 is based on claim 1 as originally filed, and includes the following further features:

(a) Structural support means within the electrode carrying member for holding the electrode carrying member in an open condition.

(b) The electrode carrying member being moisture permeable.

(c) The suction means are arranged to apply suction to the interior of the electrode carrying member when
the electrode carrying member is in the open condition.

(d) During ablation using the electrodes the suction means are operable to draw moisture released by tissue undergoing ablation through the electrode carrying member and into the suction means.

(e) The ablation is self terminating.

2.2 These features are supported by both the application as originally filed as well as by the parent application (EP-A-0898465). At least the following parts of the present divisional application (EP-A-1 415 607) support the above new features, and are also present in corresponding parts of the parent application (the present description corresponds to the description of the parent application):

(a) Claims 4 and 7.

(b) Paragraph [0010]. Original claim 1 specifies that the electrodes are moisture permeable, but this is wrong because it is inconsistent with the entire description.

(c) Paragraph [0059].

(d) Paragraph [0059].

(e) Paragraph [0025].

2.3 For these reasons claim 1 meets the requirements of Articles 76(1) and 123 (2) EPC.
3. Inventive step

3.1 The technical problems to which the application relates are set out in paragraphs [0005] and [0007] as follows:

(a) "the depth of ablation using RF techniques can only be estimated by physician since no feedback can be provided as to actual ablation depth" and

(b) "in prior art RF devices the water drawn from the tissue creates a path of conductivity through which current traveling through the electrodes will flow. This can prevent the current from traveling into the tissue to be ablated. Moreover, the presence of this current path around the electrodes causes current to be continuously drawn from the electrodes. The current heats the liquid drawn from the tissue and thus turns the ablation process into a passive heating method in which the heated liquid around the electrodes causes thermal ablation to continue well beyond the desired ablation depths".

3.2 The solution to these problems is afforded by the features of claim 1, which requires the electrode carrying member to be moisture permeable, and that it is coupled to a suction means arranged to apply suction to the interior of the electrode carrying member when the electrode carrying member is in the open condition and, during ablation using the electrodes, operable to draw moisture released by tissue undergoing ablation through the electrode carrying member and into the
suction means to substantially prevent formation of a low impedance liquid layer around the electrodes when ablation is carried out.

Suction ensures removal of the moisture from the ablation site, thereby preventing formation of a liquid layer around the electrodes. Thus, there is no liquid conductor at the ablation area such that dehydration of the ablated tissue provides an impedance and, when the desired depth of ablation has been reached, the impedance is sufficiently high to substantially stop the flow of current into the tissue. The ablation is, therefore, self-terminating.

3.3 D1 relates to tissue ablation apparatus in which a balloon is filled with electrolyte solution which flows out of the balloon in order to promote effective delivery of RF energy to the tissue. Thus, in D1, far from removing any conducting fluid from the vicinity of the ablation electrodes, electrolytic solution is deliberately provided at the surface to be ablated. It would be against the teaching of this document to provide a suction means (for example as disclosed in D2) whose effect would be to remove the fluid which is deliberately provided. Consequently, the person skilled in the art would not transfer this teaching of D2 to the apparatus of D1.

3.4 D2 describes a multifunctional device for insertion in an anatomical cavity and comprising an inflatable bladder and an absorbing material carried by the bladder. Although D2 does mention an ablation procedure in passing (column 2, line 13) it does not describe any apparatus for use in tissue ablation. It does, however,
describe suction means for aspirating fluid from the operation site.

However, since D2 does not relate to ablation apparatus, and since the problem set out in the application is specific to ablation apparatus, the person skilled in the art would have no cause to read D2 in search of a solution to the present problem. This document is not relevant to the present application, accordingly.

3.5 D3 describes an ablation device which uses an impermeable inflatable bladder with external electrodes for contact with endometrial tissue. There is no discussion of the problems caused by fluid at the interface between the electrodes and the tissue, nor does it disclose a suction means for aspirating fluids at the operation site. Therefore, D3 also provides no help in addressing the problems which are identified in the present application.

3.6 Since neither the problem nor its solution is known from the prior art, claim 1 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 the first instance with the order to grant a patent on the basis of the following application documents:

   - Claims 1 to 13 filed on 3 March 2009.
   - Description pages 1 and 3 filed on 3 March 2009.
   - Description pages 2 and 9 filed with the grounds of appeal dated 17 April 2007
   - Description pages 5 to 8 and 10 to 27 as originally filed.
   - Figures 1 to 20 as published.

The Registrar

The Chairman

D. Sauter

M. Noël