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Datasheet for the decision of 13 April 2015

Case Number: T 1879/11 - 3.2.02

Application Number: 04733277.0

Publication Number: 1631209

IPC: A61B18/14

Language of the proceedings: EN

Title of invention:
MEDICAL DEVICE USING A COILED ELECTRODE

Patent Proprietor:
Trod Medical

Opponent:
Ein-Gal, Moshe

Headword:

Relevant legal provisions:
EPC Art. 83, 84, 123(2), 123(3), 54, 56

Keyword:
Inventive step (no) - main request
Clarity, sufficiency of disclosure (yes) - auxiliary request 1
Added subject-matter, extension of scope of protection (no) - auxiliary request 1
Novelty and inventive step (yes) - auxiliary request 1

Decisions cited:
G 0009/91

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Case Number: T 1879/11 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 13 April 2015

Appellant: (Patent Proprietor)	Trod Medical 118-122 Avenue de France 75013 Paris (FR)
Representative:	Pronovem Office Van Malderen Avenue Josse Goffin 158 1082 Bruxelles (BE)
Appellant: (Opponent)	Ein-Gal, Moshe 30 Azar Street Ramat Hasharon 47203 (IL)
Representative:	Becker Kurig Straus Patentanwälte Bavariastrasse 7 80336 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 4 July 2011 concerning maintenance of the European patent No. 1631209 in amended form.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	M. Stern
	P. L. P. Weber

Summary of Facts and Submissions

I. Appeals were lodged by the opponent and by the patent proprietor against the interlocutory decision of the Opposition Division, posted on 4 July 2011, concerning the maintenance of European patent No. 1 631 209 in amended form. In the decision under appeal it was held that the patent as amended according to auxiliary request 1 satisfied the requirements of Articles 83, 54 and 56 EPC in view of the following documents:

E1: US-A-2002/0 147 446
E2: US-A-2002/0 049 439.

II. The patent proprietor filed a notice of appeal on 14 September 2011, paying the appeal fee the same day. A statement setting out the grounds of appeal was filed on 9 November 2011.

III. The opponent filed a notice of appeal and a statement setting out the grounds of appeal on 18 August 2011, paying the appeal fee the same day.

The opponent requested that the decision under appeal be set aside and that the patent be revoked.

IV. In the following, the appellant-patent proprietor will be referred to as the "proprietor", and the appellant-opponent as the "opponent".

V. The Board summoned the parties to attend oral proceedings by summons dated 23 January 2015.

VI. Although duly summoned, the opponent did not attend the oral proceedings on 13 April 2015. Before the start of the oral proceedings, the Board's registrar asked the

representative's office whether the opponent would be attending the oral proceedings. The answer was no. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued without that party.

The proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted or, in the alternative, that the appeal of the opponent be dismissed, or that the patent be maintained on the basis of one of the auxiliary request 2, filed with letter dated 17 January 2012, and the auxiliary request 3, filed with letter dated 10 March 2015.

VII. Claim 1 of the main request (i.e. claim 1 of the patent as granted) reads as follows:

"A medical device (1) adapted for the ablation of a target volume inside an anatomical organ, said medical device (1) comprising as elements a main body (2), stabilising means (3) for stabilising the medical device relatively to the organ and heating means in the form of a bipolar electrode (10) comprising parts activable [sic] by an external radiofrequency generator for heating said target volume, wherein said bipolar electrode (10) comprises a first element having the form of a central anchoring member (5), and a second element having the form of at least two concentric rigid helices (4',4",...) of different predetermined diameters (D) and predetermined length (L), said helices surrounding the central anchoring member (5) to form a cage-like structure around said anchoring member (5) when deployed according to a working configuration, one of the helices being activatable independently so as to form a first pole while a second pole is formed either by the central anchoring member or by the helix

of smaller diameter than the helix forming the first pole."

VIII. Claim 1 of auxiliary request 1 (which the Opposition Division held to be allowable) reads as follows (amendments to claim 1 of the main request are highlighted by the Board):

"A medical device (1) adapted for the ablation of a target volume inside an anatomical organ, said medical device (1) comprising as elements a main body (2), stabilising means (3) for stabilising the medical device relatively to the organ and heating means in the form of a bipolar electrode (10) comprising parts activable [sic] by an external radiofrequency generator for heating said target volume, wherein said bipolar electrode (10) comprises a first element having the form of a central anchoring member (5), and a second element having the form of at least two concentric rigid helices (4',4",...) of different predetermined diameters (D) and predetermined length (L), said helices surrounding the central anchoring member (5) to form a cage-like structure around said anchoring member (5) when deployed according to a working configuration, wherein the central anchoring member (5) and the at least two helices (4', 4'') each have a proximal end that is configured to be linked to the external radiofrequency generator so that one of the helices ~~being~~ is activatable independently so as to form a first pole while a second pole is formed either by the central anchoring member or by the helix of smaller diameter than the helix forming the first pole."

Claims 2 to 13 are dependent claims.

IX. The arguments of the opponent relevant for the present decision are summarised as follows:

- The definition in claim 1 of the granted patent of "one of the helices being activatable independently" only stated that the activation of one of the helices was independent of the activation of other elements. There was no further explanation given in the patent as to the interpretation of the term "independent". The claim (in the granted version as well as in the auxiliary requests) did not contain any feature related to "operational modes" or elements that would allow a user to select between different operational modes, as suggested by the proprietor. The claim defined two separate alternatives, one in which the second pole was formed by the central anchoring member, and another in which the second pole was formed by the helix of smaller diameter than the helix forming the first pole.

- Claim 1 of the granted patent lacked novelty and inventive step, having regard to the different embodiments disclosed in E1. Paragraphs [0023] and [0024] of E1 described a device having a pair of bipolar, concentric electrodes with a central rod for motion stabilisation. Although it was not explicitly mentioned that the two helices could have different widths, the remaining description, for example Figure 6, clearly showed that they could. Moreover, the skilled person was led to immediately combine the contents of Figures 2 to 5 and Figure 6, since the only difference described was that the electrodes were now a pair of bipolar concentric helices.

- The feature added to claim 1 of auxiliary request 1 ("wherein the central anchoring member and the at least two helices each have a proximal end that is configured

to be linked to the external radiofrequency generator") was not clear (Article 84 EPC) and raised further issues under Article 83 EPC. The feature was moreover unallowable under Article 123(2) and (3) EPC. In particular, it was not clear what the expression "configured to be linked" implied.

- The subject-matter of claim 1 of auxiliary request 1 was not novel, at least not inventive in view of E1, and further not inventive in view of E2. The added claim feature of the helices being "configured to be linked" did not add any technical content. Thus, the discussion of novelty and inventive step was the same as for the granted claim.

X. The arguments of the proprietor relevant for the present decision are summarised as follows:

- Claim 1 (of the granted patent and of the auxiliary requests) defined a device comprising a bipolar electrode having at least three components, viz. a central anchoring member and two concentric rigid helices of different diameters surrounding the central anchoring member. It defined, moreover, "one of the helices being activatable independently ...". The term "independently" had to be given its proper meaning, expressing the possibility that one helix could be activated without requiring dependence on the other helix, in the sense that the other helix did not need to be activated as well for functioning as a bipolar electrode. It followed that a correct interpretation of claim 1 was that the medical device was configured to work according to at least two operational modes wherein one helix formed a first pole and the second pole was formed, in a first operational mode, by the helix of smaller diameter and, in a second operational

mode, by the central anchoring member. The operational modes defined different target volumes and hence allowed the user to select and even to switch between them to obtain a more selective ablation. E1 did not disclose any of the electrodes with the suitability of being used with such operational modes.

- In the embodiment of paragraph [0024] of E1, the central rod was insulated and could therefore not be used as the second pole of the bipolar electrode, as defined in claim 1. Hence, no ablation of tumour tissue was feasible around the central rod, whereby cancer dissemination could occur upon insertion into the tumour. Even if this embodiment was combined with the embodiment of Figure 6A which depicted concentric helices with different diameters, the skilled person would not arrive at the device of claim 1 of the patent.

- Regarding auxiliary request 1, consideration of Article 123(2) EPC fell outside the scope of the present appeal proceedings. In any case, the features added to claim 1 of the patent had a proper basis in the original application on page 10, lines 31 to 32 and page 11, lines 23 to 24, and introduced a further limitation to the device of claim 1 of the granted patent. The expression "configured to be linked" to a radiofrequency generator was clear, as it specified that the electrode components were suitable to be linked to the generator. The skilled person was left in no doubt as to how such components would have to be devised.

- The device of claim 1 of auxiliary request 1 was also novel and inventive over the cited prior art. The embodiment of paragraph [0024] of E1 lacked the claimed

feature that each of the central anchoring member and the two helices were suitable to be linked to the external radiofrequency generator. This feature allowed the user to select and even to switch between the target volumes to obtain a more selective ablation. The objective technical problem was to precisely control the region of tissue to be destroyed while preserving the surrounding healthy tissue, as indicated in paragraphs [0007] and [0011] of the patent. E1 was concerned with tissue ablation by moving the electrodes in a controlled manner. The skilled person therefore had no reason to combine the different embodiments of E1 in such a way as to obtain the device of claim 1. Moreover, E2 disclosed mainly monopolar electrode configurations. Only in Figure 15 was a bipolar electrode disclosed, which, however, was similar to that of Figure 6 of E1.

Reasons for the Decision

1. The appeals are admissible.

2. Main request

2.1 The patent relates to a device for radiofrequency ablation of a tissue volume, such as a tumour, which allows the destruction of said unsafe tissue volume while preserving the surrounding healthy tissue (paragraphs [0010] and [0011] of the patent).

2.2 The device defined in claim 1 of the patent is defined as comprising, in essence, a bipolar electrode comprising parts activatable by an external radiofrequency generator, wherein the bipolar electrode comprises a central anchoring member and at least two

concentric helices of different diameters surrounding the central anchoring member, one of the helices being activatable independently so as to form a first pole while a second pole is formed either by the central anchoring member or by the helix of smaller diameter than the helix forming the first pole.

2.3 It is noted that when claim 1 refers to "concentric helices", what is meant is that the helices are coaxial, as becomes clear from inspection of Figures 3A and 3B of the patent. Moreover, the "diameter" of a helix appears to designate the extension of the helix in radial direction, as results from paragraphs [0050] and [0051] of the patent.

2.4 The definition in claim 1 according to which one of the helices is activatable *"independently"* (of either the central anchoring member or another of the helices of smaller diameter) has been interpreted in different ways by the parties.

The proprietor understands this definition to limit the claimed subject-matter to a (single) device configured to work according to two operational modes, one mode in which the second pole is formed by the central anchoring member, and a second mode in which the second pole is formed by the smaller diameter helix.

The Board disagrees with this view. Claim 1 is not addressed at limiting the way the *external* radiofrequency generator selects the outputs to which the different components of the bipolar electrode are connected. Instead, the claim specifies a bipolar electrode as an entity constructed so that one of the helices may be a first pole which is activatable independently of any other component of the electrode

assembly (which does not form the bipolar pair), while the second pole is **either** the central anchoring member **or** a helix of smaller diameter. That is, the claim does not require, for example, that *each one* of the central anchoring member and the helix (or helices) of smaller diameter is activatable as an electrode pole (the "second pole"). This way of interpreting claim 1 seems to be consistent with the original application, notably original claim 5, or original paragraphs [0057] and [0058].

2.5 Novelty

Document E1 discloses different embodiments of a bipolar electrode of a device for radiofrequency ablation of tissue. None of these embodiments comprises all the features of the electrode according to claim 1:

(i) According to Figure 5 and paragraph [0069], the bipolar electrode comprises a single helix (52) and central rod (70). Consequently, it does not have at least two concentric helices of different diameters as defined in claim 1.

(ii) In Figures 6A and 6B and paragraphs [0071] and [0072], the bipolar electrode is formed of concentric helices (82, 88) of different diameters, lacking, however, a central anchoring member as defined in claim 1.

(iii) In the bipolar electrode disclosed in paragraph [0023], one pole is formed from what is termed a "multi-helix electrode", while the other pole is formed by a central rod. Hence, unlike in claim 1, these helices are disclosed to be "concentric" helices and they are not disclosed to have different diameters.

Moreover, since one of the poles is a "multi-helix electrode" the different helices forming this "multi-helix" are not activatable independently of one another, as claim 1 defines (point 2.4 above).

(iv) The bipolar electrode disclosed in paragraph [0024] is formed of concentric helices having an insulated central rod for motion stabilisation. The helices are not disclosed to be of different diameters, as defined in claim 1.

Since none of the mentioned embodiments of E1 comprises all the features of the electrode according to claim 1, the subject-matter claimed satisfies the novelty requirement of Article 54(1) and (2) EPC.

2.6 Inventive step

2.6.1 Of the aforementioned embodiments disclosed in E1, the embodiment mentioned in paragraph [0024] (point 2.5(iv) above) is seen as the closest prior art. The device of claim 1 differs from this embodiment in that the two concentric helices have different diameters.

Said paragraph [0024] merely indicates that the electrode is formed of bipolar concentric helices with an insulated central rod for motion stabilisation, but gives no further information on the construction of the concentric helices.

2.6.2 The skilled person would therefore search elsewhere in E1 for such information. In the embodiment of Figures 6A and 6B and paragraphs [0071] and [0072] the bipolar concentric helices are disclosed, in particular, with different diameters (point 2.5(ii) above). It would therefore involve no inventiveness to

devise also the bipolar concentric helices of the closest prior-art embodiment of paragraph [0024] with different diameters.

2.6.3 The proprietor argued that in the embodiment of paragraph [0024] of E1, the central rod was insulated and could therefore not be used as the second pole of the bipolar electrode, as claim 1 defined.

The Board considers that this argument is of no relevance, since what is anticipated by this embodiment of E1 is another alternative defined in claim 1, namely the alternative in which the first and second poles of the bipolar electrode are the two concentric helices. Contrary to the view of the proprietor, the claim does not require another operational mode establishing a bipolar pair with the central rod.

Consequently, the device of claim 1 of the main request does not involve an inventive step in the sense of Article 56 EPC.

3. Auxiliary request 1

3.1 Claim 1 of auxiliary request 1 adds to claim 1 of the granted patent the limitation that the central anchoring member and the at least two concentric helices *"each have a proximal end that is configured to be linked to the external radiofrequency generator"*.

3.2 This feature was objected to by the opponent (first in its statement of grounds of appeal) pursuant to Articles 123(2) and (3), 84 and 83 EPC.

3.3 The proprietor suggested that consideration of Article 123(2) EPC fell outside the scope of the present appeal proceedings.

It is true that the opposition was not based on Article 100(c) EPC. However, as correctly pointed out by the opponent, in case of amendments to the claims or other parts of a patent in the course of opposition or appeal proceedings, such amendments are to be fully examined as to their compatibility with the requirements of the EPC, e.g. with regard to the provisions of Article 123(2) and (3) EPC (G 9/91, Reasons, point 19).

3.4 The features added to claim 1 of the granted patent have a proper basis in the original application on page 10, lines 31 to 32 and page 11, lines 23 to 24. They are therefore in accordance with Article 123(2) EPC.

3.5 The Board considers that the definition of the ends of the central member and the helices as being "configured to be linked" to a radiofrequency generator clearly specifies that the ends (of *each one* of the central member and of the helices) are suitable to be linked to the generator, or that they enable their linking to the generator. The expression therefore satisfies the clarity requirement of Article 84 EPC.

3.6 Consequently, in contrast to claim 1 of the granted patent, claim 1 of auxiliary request 1 requires that *each one* of the central anchoring member and the helix (or helices) of smaller diameter is activatable as an electrode pole (the "second pole"). This therefore represents a technical limitation to the device of claim 1 of the patent as granted, thereby restricting

the scope of protection, in accordance with Article 123(3) EPC.

3.7 There can be no doubt either that the skilled person would be capable of devising electrode ends such that they are suitable to be linked to a radiofrequency generator. They would just have to be conductive, for example. Moreover, paragraphs [0049] and [0053] of the patent describe a corresponding embodiment. Therefore, the requirements of Article 83 EPC are likewise met.

3.8 Novelty and inventive step

3.8.1 As indicated under point 2.5 above, each of the embodiments disclosed in E1 lacks at least one of the features recited in claim 1 of the granted patent. Claim 1 of auxiliary request 1 contains a further limitation stipulating that *each* of the concentric helices and the central member has to be suitable to be linked to the external radiofrequency generator. The claimed subject-matter is therefore also novel over E1.

3.8.2 This additional limitation further distinguishes the subject-matter claimed from the embodiment of paragraph [0024] of E1, in which the central rod is insulated. Hence, the prior-art embodiment of paragraph [0023] (point 2.5(iii)) is now arguably a more promising starting point. In this embodiment, the bipolar electrode has one pole formed from what is termed a "multi-helix electrode", while the other pole is formed by a central rod. Since one of the poles is a "multi-helix electrode", the different helices forming this "multi-helix" are not activatable independently of one another, as claim 1 defines (point 2.4 above). Moreover, the helices are not disclosed as concentric

helices with different diameters, as also defined in claim 1.

3.8.3 Whilst each of the bipolar electrodes disclosed in E1 (point 2.5 above) has just two poles for connection with the generator, in the claimed device each of the central anchoring member and the (at least) two helices are capable of being linked to the external radiofrequency generator. This allows the user to select and even to switch between different target volumes to obtain a more selective ablation.

The objective technical problem to be solved by these differentiating features is hence to precisely control the region of tissue to be destroyed while preserving the surrounding healthy tissue, as stated in paragraphs [0007] and [0011] of the patent.

3.8.4 E1 does not identify or deal with this problem, but is concerned instead with tissue ablation by moving the electrodes in a controlled manner (paragraph [0022]). It would hence be only with the benefit of hindsight that the different bipolar electrodes of E1 could be combined in such a way to obtain a device with all the features defined in claim 1.

3.8.5 Document E2 discloses a bipolar electrode only in Figure 15. The electrode is formed of concentric helices of different diameters, but has no central anchoring member. Hence, in this respect, E2 does not go further than the embodiment of Figures 6A and 6B of E1 (mentioned under point 2.5(ii) above).

3.8.6 As a consequence, the subject-matter of claim 1 of auxiliary request 1 satisfies the requirement of inventive step in the sense of Article 56 EPC. This

applies a fortiori to the preferred embodiments defined in dependent claims 2 to 13.

4. Since none of the objections raised is an obstacle to maintaining the patent on the basis of auxiliary request 1, there is no need for the Board to consider auxiliary requests 2 and 3.

Order

For these reasons it is decided that:

The appeal of the opponent is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated