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D E C I S I O N
of 29 September 1999

Case Number: T 0035/99 - 3.2.2

Application Number: 92923107.4

Publication Number: 0746376

IPC: A61M 31/00

Language of the proceedings: EN

Title of invention:
Pericardial access via the right auricle

Applicant:
Georgetown University

Opponent:
-

Headword:
Pericardial access/GEORGETOWN UNIVERSITY

Relevant legal provisions:
EPC Art. 52(4)

Keyword:
"Method for treatment of the human body by surgery (yes)"

Decisions cited:
T 0329/94, T 0182/90, T 0820/92, T 0082/93, T 0116/85, G 0005/83

Headnote:
Follows

Headnote:
In contrast to procedures whose end result is the death of the living being "under treatment", either deliberately or incidentally (eg the slaughter of animals or methods for measuring biological functions of an animal which comprise the sacrificing of said animal, cf. T 182/90), those physical interventions on the human or animal body which, whatever their specific purpose, give priority to maintaining the life or health of the body on which they are performed, are "in their nature" methods for treatment by surgery within the meaning of Article 52(4) EPC.

The terms "treatment" and "surgery" in Article 52(4) EPC cannot be considered as constituting two distinct requirements for the exclusion provided therein. The exclusion encompasses any surgical activity, irrespective of whether it is carried out alone or in combination with other medical or non-medical measures.

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0035/99 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 29 September 1999

Appellant: Georgetown University
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Washington, D.C. 20057 (US)

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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 6 July 1998 refusing European patent application No. 92 923 107.4 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: R. T. Menapace
M. G. Noël

Summary of Facts and Submissions

I. European patent application No. 92 923 107.4, filed as an international application on 23 October 1992 and published under No. WO 93/07931, was refused by the examining division by a decision dated 6 July 1998. The refusal pursuant to Article 97(3) EPC was based on claims 1 to 10 as filed with a letter dated 21 August 1995.

II. Claim 1 reads as follows:

"A method for transvenously accessing the pericardial space between a heart and its pericardium in preparation for a medical procedure, said method comprising the following steps:
(a) guiding a catheter downstream through one of the venae cavae to the right atrium;
(b) guiding said catheter through the right atrium and into the right auricle; and
(c) accessing the pericardial space with said catheter by penetrating through the wall of the right auricle."

III. The reason given for the refusal was that the methods according to Claim 1 as well as those according to the other claims were of surgical character and were therefore excluded from patentability under Article 52(4) EPC. This finding was mainly based on the principle set out in decision T 182/90, namely that the term "treatment by surgery" may also comprise particular treatments which are not directed to the health of the human or animal body", in particular catheter insertion (paragraph 2.3 of the reasons) which

was considered as an intensive surgical technique. Reference was also made to Guidelines C-IV, 4.3, according to which "surgery" within the meaning of Article 52(4) EPC defines the nature of the treatment rather than its purpose.

IV. A notice of appeal was filed against this decision and the appeal fee was paid on 7 September 1998. The statement of grounds was received on 3 November 1998.

V. The appellant argued in substance that decision T 182/90 should be understood as meaning that

- the presence of a surgical step within the claimed sequence of steps is not sufficient by itself to cause the claimed sequence to be excluded from patentability

- "treatment" within the meaning of Article 52(4) EPC refers to a complete treatment in which a desired curative or non-curative effect is achieved.

Thus, the Guidelines, where they define "surgery", had been explicitly overruled.

Decision T 329/94, also cited in the decision under appeal, whilst not directly relevant to the present application in that it is concerned with a method for treatment of the human body by therapy, stated that

- Article 52(4) EPC should be construed narrowly

- however, the presence of just one feature which

constitutes a method for treatment of the human body renders the claim unpatentable only if said feature defines a complete treatment by therapy and not only one step in such a complete treatment (the claim falling short of defining such a complete treatment).

VI. In the oral proceedings the appellant further explained his line of reasoning by making a distinction between a "treatment" and a medical process, be the latter surgical, therapeutic or diagnostic. In his view, a claimed medical process is only excluded from patentability under Article 52(4) EPC if it has to be rated as a treatment. However, until now the jurisprudence has only defined what is not a treatment, but not given a positive definition of the term "treatment" as mentioned in Article 52(4) EPC. All the examples found in the jurisprudence are complete treatments, including those found acceptable under Article 52(4) EPC because they involved the deliberate killing of the body. It was submitted that, consequently, "treatment" within the meaning of this provision is a complete procedure with a beneficial effect on the body. The claimed method, however, did not meet either of these two criteria.

VII. Before the present decision was announced at the end of the oral proceedings held on 29 September 1999, the appellant requested that

- the decision under appeal be set aside and it be decided that the claims on which the decision under appeal was based are not excluded from patentability under Article 52(4) EPC, and

therefore that the case be remitted to the examining division for further prosecution, and

- that in the event that the Board cannot grant the first request, questions 1 to 4 set out in the letter of 27 August 1999 be submitted to the Enlarged Board of Appeal together with the additional question of whether the presence of a surgical step means that the claim is automatically excluded under Article 52(4) EPC.

The above-mentioned questions read as follows:

(1) Does a method of treatment of the human or animal body mean any non-insignificant intervention performed on the human or animal body?

(2) If yes, what is a non-insignificant intervention?

(3) If no, what is the definition of a method of treatment?

(4) For a claim to be excluded under Article 52(4) EPC, does it have to relate in its entirety to a method of treatment?

Reasons for the Decision

1. The appeal is admissible

Interpretation of Article 52(4) EPC - Exclusion of methods for treatment by surgery

2. In decision T 182/90 a comprehensive analysis is made of the meaning of the term "treatment by surgery" or "surgical treatment". In particular, it states that catheter insertion is considered as a surgical technique (point 2.3 of the reasons). It was also held that the presence of a surgical step in a multi-step method of the treatment of the human or animal body normally confers a surgical character on that method (point 2.5.1 and headnote I). On the other hand, the statement in the Guidelines for Examination in the European Patent Office (see C-IV, 4.3) that the term "surgery" defines the nature of the treatment rather than its purpose may not be true in all cases (point 2.3 of the reasons), in that a method involving the deliberate killing of an animal or treatments for similar destructive purposes do not constitute surgical treatment (points 2.3 and 2.5.2 of the reasons).

3. This Board sees no reason to deviate from the above view. In fact it believes that the exclusion of "destructive treatments" from the scope of Article 52(4) EPC is perfectly consistent with, and therefore imposes no limits on, the concept that "surgery" defines the nature of the treatment rather than its purpose (Guidelines, see above). Methods consciously ending in the treated subjects death are not **in their nature** methods of surgical treatment (point 2.5.2 of the cited decision), irrespective of whether they comprise one or more surgical steps.

4. Developing this point further, two categories of physical interventions in the human or animal body have to be clearly distinguished:

4.1 The first category embraces those interventions which, whatever their specific purpose, give priority to maintaining life or health of the human or animal body on which they are performed. This applies both to healing and to cosmetic surgery, and generally to all physical interventions aimed at altering functions of the living body (eg castration to bring about changes in body functions linked to sex), as well as to the removal of body parts (eg for transplantation).

4.2 The second category comprises all those procedures whose end result is the death of living beings "under treatment", either deliberately or incidentally (eg the slaughter of animals or the process with which decision T 182/90 is concerned). These "lethal" procedures, in accordance with their definition, involve sacrificing life, and are therefore subject to ethical considerations (see Article 53(a) EPC) and specific legal restrictions (eg criminal penalties for causing death).

4.3 The application of procedures of the first category is in general riskier and more complex. The absolute imperative to maintain life and health, especially those of a human being, has to be considered against the background of the complexity and individuality of human and animal life in its biological and mental constitution. Therefore, the effects of surgical and therapeutic measures on the life and health of the treated body, whether intended or not, cannot be foreseen with certainty; in critical situations, such as life-threatening illnesses or injuries, decisions must be taken and treatments given even if they involve a great risk under extreme time pressure. Such problems

do not arise in the case of technical procedures not designed to maintain the life or health of a human being or animal; but they are inherent in all activities in the fields of diagnosis, surgery and therapy.

5. As a consequence, the legislator has laid down a separate framework for the medical sphere, such as strict regulations governing the use of medical treatments, liability for damage caused by such treatments and criminal penalties for misuse. The question of how far patent protection should cover medical procedures also arises. The answer has a substantial bearing on the overall economic and legal risks and restraints to which medical activity is subject.

6. The appropriate legislative answer to these questions is a matter of policy, which will always be determined by a variety of medical, legal, social and other aspects, even cultural and ethical ones. It is therefore understandable that the rules governing the patentability of inventions relating to medical activities may differ, even considerably, from one patent system to another. As regards the European Patent Convention, the policy behind the exclusion of the methods set out in Article 52(4) EPC was clearly to ensure that those who carry out such methods as part of the medical treatment of humans or the veterinary treatment of animals should not be inhibited by patents (see decisions T 116/85 (OJ 1989, 13), T 82/93 (OJ 1996, 274) and G 5/83 (OJ 1985, 64)).

7. In the light of this clear and deliberate choice on the

part of the legislator, the terms "treatment" and "surgery" in Article 52(4) EPC cannot be considered as constituting two distinct requirements for the exclusion. For a given patient, the optimal or only available treatment could not be administered if even a single part or step thereof - and most treatments comprise several steps - were covered by patent protection. In the extreme, the physician would have to deny life-saving assistance in order not to infringe a patent. Indeed, as a matter of principle the patent protection for a method as defined by the features of a claim includes its use (or "carrying out") without having regard to the intentions of the user. Moreover, it would be quite difficult if not impossible to define clearly whether a surgical method is a complete or a non-insignificant treatment per se, or as carried out in an individual case. Therefore, such criteria would run counter to clarity and legal certainty.

8. It follows that the wording "methods for treatment of the human or animal body by surgery or therapy" means any (by its nature) surgical or therapeutical method which can be carried out (or "practised" - the term used in the same sentence of Article 52(4) EPC in relation to diagnostic methods) as such on the human or animal body. Consequently, as the uniform jurisprudence has held (T 820/92 (OJ 1995, 113), T 82/93 (OJ 1996, 274) and T 182/90 cited above), a claim is not allowable under Article 52(4), 1st sentence, EPC if it includes at least one feature defining a physical activity or action (eg a method step) which constitutes a "method for treatment of the human body by surgery or therapy";) and it is irrelevant whether the method in question is susceptible of being carried out in

isolation or only in combination with other methods which together achieve the intended medical effect.

The present application

9. Each of the claims of the present application relates to a method for accessing the pericardial space between the heart and the pericardium by penetrating through the wall of the right auricle with a catheter or an electrode, which has been previously guided downstream through one of the venae cavae and the right atrium (features (a) to (c)). This method seeks to improve upon the conventional methods for diagnosing and treating the heart via the pericardial space by providing a method for safely and reliably introducing a catheter and/or electrodes into the pericardial space (page 4, lines 4 to 7 of the description) for delivery of electricity to the heart muscle (page 3, line 20 of the description) and/or for introducing pharmacologic agents directly into the pericardial sac (page 3, line 24 of the description). The alleged invention aims at avoiding the disadvantages and risks of the known methods of gaining access to the pericardial space without using thoracotomy (see page 1, line 26 to page 3, line 20 of the description).

10. Accordingly, all the methods claimed in the application involve catheterisation as part of a medical process and therefore qualify as "methods for treatment of the human or animal body by surgery" which is not regarded as susceptible of industrial application (Article 52(4) EPC). The insertion of "in preparation for a medical procedure" in claim 1 cannot change this, because - apart from being neither a technical nor a functional

feature of the method as claimed - it does not change the surgical nature of the claimed method (see point 8 above). It is also evident that the claims do not relate to any technical feature of a particular device for practising the claimed method, in particular not to catheters or electrodes, in contrast to the subject-matter in question in decision T 329/94, which was confined to a method for operating a particular device (point 6 of the reasons).

11. The Board therefore sees no need to refer to the Enlarged Board of Appeal any of the questions formulated by the applicant or any other question concerning surgical methods under Article 52(4) EPC. The case did not raise any new point of law which could not have been decided in conformity with the comprehensive and uniform jurisprudence which exists on the question posed by the applicant. Thus there is no reason for allowing his request under Article 112(1)(a) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Fabiani W. D. Weiß