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**D E C I S I O N**  
**of 13 July 2006**

**Case Number:** T 1102/02 - 3.2.02

**Application Number:** 95119588.2

**Publication Number:** 0723785

**IPC:** A61M 16/00

**Language of the proceedings:** EN

**Title of invention:**

Method and apparatus for determining a transfer function for a connection system in a ventilator system

**Applicant:**

Maquet Critical Care AB

**Opponent:**

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**Headword:**

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**Relevant legal provisions:**

EPC Art. 52(4)

**Keyword:**

"Diagnostic method (no)"  
"Method for treatment (no)"

**Decisions cited:**

G 0001/04, T 0383/03, T 0182/90

**Catchword:**

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Case Number: T 1102/02 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 13 July 2006

**Appellant:** Maquet Critical Care AB  
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**Representative:** Stein, Jan Anders Lennart  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 5 July 2002  
refusing European application No. 95119588.2  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** T. Kriner  
**Members:** M. Noel  
A. Pignatelli

## Summary of Facts and Submissions

I. European patent application No. 95 119 588.2 was refused by decision of the examining division dated 5 July 2002 on the ground that the independent method claim 5 related to a diagnostic method performed on the human body, which was excluded from patentability by Article 52(4) EPC.

The reasons of the first instance were that the only aim of the method according to claim 5 was to determine the characteristics of the lungs and the respiratory system of the individual to be treated. This method, therefore, could be interpreted as a diagnostic method to provide information for improved treatment of a patient.

II. The appellant (applicant) lodged an appeal against this decision by notice received on 14 August 2002 and paid the appeal fee on the same day. A statement setting out the grounds of appeal was filed on 14 October 2002.

III. By a communication of the Board dated 15 February 2006 the appellant was informed that claim 5 of the main request could also be objected to under Article 52(4) EPC as a method for treatment of the human body by surgery, should the connection to the patient be considered as a direct intervention on the living body and, consequently, as a surgical step.

IV. Oral proceedings were held on 7 June 2006 during which the appellant filed amended sets of claims according to a further auxiliary request.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 12 filed with letter of 30 January 2002 (main request), or on the basis of the first auxiliary request filed during the oral proceedings or on the basis of the second auxiliary request filed with letter of 30 January 2002.

After deliberation by the Board, the appellant was informed that the decision would be given in writing.

V. Claim 5 of the main request reads as follows:

"A method for determining at least one transfer function designating how a respiratory system (8) of a living creature connected to a ventilator system (2), comprising a ventilator unit (4) for connection to the respiratory system (8), via a connection system (6) for supplying and carrying off a breathing gas to/from the respiratory system (8) with a predetermined gas flow pattern in respect to pressure and flow, influences the predefined gas flow pattern, comprising the methodological stages:

connecting the connection system (6) to the ventilator unit (4);

supplying a gas with a first test gas flow pattern from a gas-regulating unit (12A, 12B, 12C, 14A, 14B, 14C, 18, 46) in the ventilator unit (4);

measuring, in a measurement unit (20, 22; 62, 64), an ensuing first response gas flow pattern for the gas;

determining a first transfer function from the first test gas flow pattern and the first response gas flow pattern;

after connection of the connection system (6) to the respiratory system (8) supplying a gas with a second test gas flow pattern from the gas-regulating unit (12A, 12B, 12C, 14A, 14B, 14C, 18, 46) in the ventilator unit (4);

measuring, in a measurement unit (20, 22; 62, 64), an ensuing second response gas flow pattern for the gas; and

determining the respiratory system's (8) influence on the gas flow pattern from the second test gas flow pattern, the second response gas flow pattern and the determined first transfer function."

- VI. At the oral proceedings, the appellant submitted that in claim 5 the expression "after connection of the connection system (6) to the respiratory system (8) had to be construed only as a preliminary condition for the performance of the subsequent steps of the method, but did not form a part of the claimed subject-matter. The scope of claim 5, therefore, did not include the previously performed connection of the ventilator system to the patient, thus excluding a direct intervention on the living body. Furthermore, the appellant argued that the method steps only regard the internal operation of the device and concern the technical operation of generating and detecting gas flow patterns and thus fall in terms of design and performance within the exclusive competence and responsibility of the technician skilled in respirator technology.

## Reasons for the Decision

1. The appeal is admissible.
2. *Diagnostic method*

In the opinion G 1/04 (OJ EPO 2006, 334) the Enlarged Board of Appeal came to the following conclusion:

"In order that the subject-matter of a claim relating to a diagnostic method practised on the human or animal body falls under the prohibition of Article 52(4) EPC, the claim is to include the features relating to:

- (i) the diagnosis for curative purposes *stricto sensu* representing the deductive medical or veterinary decision phase as a purely intellectual exercise,
- (ii) the preceding steps which are constitutive for making that diagnosis, and
- (iii) the specific interactions with the human or animal body which occur when carrying those out among these preceding steps which are of a technical nature."

Claim 5 defines a method for determining at least one transfer function designating how a respiratory system of a living creature (a patient) connected to a ventilator system influences a predefined gas flow pattern, i.e. the pressure and flow characteristics over time of the supplied gas.

The technical features which form the steps of the method, all aim at determining the influence of the respiratory system on the gas flow pattern. More specifically, the method according to claim 5 determines at first the transfer function for the connection system without connection to the patient, by means of a first test gas routine (test lung described in relation to figure 2), and then the influence of the respiratory system on the gas flow pattern from said previously determined transfer function and a second test gas routine performed after connection of the connection system to the patient.

This method, therefore, is performed in order to compensate for the flow of gas delivered to the patient with respect to the target value, without any relationship with a diagnostic method considered as part of a medical treatment of humans for curative purposes (see G 1/04, point 5).

Further, claim 5 does not include any feature relating to a diagnosis for curative purposes strictu sensu representing the deductive medical or veterinary decision phase as a purely intellectual exercise, nor the preceding steps which are of a technical nature and constitutive for making the diagnosis, i.e. the examination phase involving the collection of data, the comparison of these data with standard values, and the finding of any significant deviation (the symptom) during the comparison.

Claim 5, therefore, does not refer to a diagnostic method excluded from patentability by Article 52(4) EPC.

3. *Method for treatment by surgery or therapy*

The method according to claim 5 implies that a living creature is connected with the apparatus. The connection is carried out through intubation which is a surgical step.

According to the jurisprudence of the boards of appeal a single surgical step in a method for treatment of the human or animal body confers surgical character to the method (see T 182/90, OJ EPO 1994, 641).

Methods for treatment of the human or animal body by surgery or therapy are considered not to be patentable inventions (see Article 52(4) EPC).

The question therefore arises whether the method according to claim 5 is a method for treatment of the human or animal body i.e. a method suitable or potentially suitable for maintaining or restoring the health, the physical integrity, and the physical well being of a human being or an animal and to prevent diseases (see T 383/03, OJ EPO 2005, 159, points 3.2 to 3.4).

With respect to this question it has to be observed that the claim does not contain any feature describing how the patient is connected to the connection system and that the method as a whole represents a technical method for determining a system parameter (the transfer function) which is then used to adjust the functioning of the ventilator system (see point 2 above).



Claim 5, therefore, is not concerned at all with a method for treatment of the human or animal body within the meaning of Article 52(4) EPC.

Thus, Article 52(4) EPC does not apply in the present situation.

4. *Remittal*

Since the decision of refusal was exclusively based on the ground of exclusion from the patentability under Article 52(4) EPC, now removed, the Board finds it appropriate to remit the case to the first instance for further prosecution.

**Order**

**For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The case is remitted to the examining division for further prosecution on the basis of claims 1 to 12 filed with letter of 30 January 2002 (main request).

The Registrar:

The Chairman:

A. Counillon

T. Kriner