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**Datasheet for the decision  
of 8 June 2011**

**Case Number:** T 1680/08 - 3.2.02

**Application Number:** 04007355.3

**Publication Number:** 1579882

**IPC:** A61M 16/00

**Language of the proceedings:** EN

**Title of invention:**

Non-invasive method and apparatus for optimizing the  
respiration for atelectatic lungs

**Applicant:**

Böhm, Stephan, Dr.

**Opponent:**

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**Headword:**

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**Relevant legal provisions:**

EPC Art. 53(c), 111

**Relevant legal provisions (EPC 1973):**

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**Keyword:**

"Method for treatment by therapy (yes; main and first  
auxiliary request)"

"Remittal (yes; apparatus claims)"

**Decisions cited:**

G 0001/07, T 1102/02, T 0245/87

**Catchword:**

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Case Number: T 1680/08 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 8 June 2011

**Appellant:** Böhmer, Stephan, Dr.  
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**Representative:** Joppich, Martin  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 3 April 2008  
refusing European application No. 04007355.3  
pursuant to Article 97(2) EPC.

**Composition of the Board:**

**Chairman:** M. Noël  
**Members:** P. L. P. Weber  
A. Pignatelli

## Summary of Facts and Submissions

I. The appeal is against the decision of the Examining Division posted on 3 April 2008 to refuse European patent application No. 04007355.3, mainly because the subject-matter of claim 1 was considered to be a method for treatment of the human body by therapy excluded from patentability pursuant to Article 53(c) EPC.

A notice of appeal was filed on 3 June 2008 and the appeal fee paid on the same day. A statement setting out the grounds of appeal was filed on 1 August 2008.

II. Oral proceedings took place on 8 June 2011.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 40 of the main request received on 1 August 2008 or of the claims of the first auxiliary request received on 29 March 2011 or on the basis of claims 1 to 20 of the second auxiliary request filed during the oral proceedings before the Board.

III. Claim 1 of the main request reads as follows:

"1. Method for determining airway pressure levels at which certain lung conditions of a lung ventilated by an artificial ventilator occur, comprising the steps of:

- a) obtaining data samples of the CO<sub>2</sub> concentration of the expired gas over a single breath,
- b) selecting a plurality of data samples from said obtained data samples,

- c) calculating a mean tracing value being sensitive to changes of alveolar dead space on the basis of said selected data samples,
- d) repeating steps a), b) and c) for obtaining a plurality of mean tracing values, and
- e) changing the airway pressure of the artificial ventilator, wherein from the observation of the resulting course of the plurality of calculated mean tracing values the airway pressure level at which alveolar opening or lung overdistension or lung open condition or alveolar closing occurs is detected."

Claim 1 according to the first auxiliary request reads as follows :

"1. Method for determining in real time airway pressure levels at which certain lung conditions of a lung ventilated by an artificial ventilator occur, comprising the steps of:

- a) obtaining automatically data samples of the CO<sub>2</sub> concentration of the expired gas over a single breath,
- b) selecting automatically a plurality of data samples from said obtained data samples,
- c) calculating automatically a mean tracing value being sensitive to changes of alveolar dead space on the basis of said selected data samples,
- d) repeating steps a), b) and c) for obtaining a plurality of mean tracing values, and
- e) changing the airway pressure of the artificial ventilator, wherein from the observation of the resulting course of the plurality of calculated mean tracing values the airway pressure level at which alveolar opening or lung overdistension or lung open

condition or alveolar closing occurs is automatically detected."

Claim 1 according to the second auxiliary request reads as follows :

"1. Apparatus for determining the status of a lung ventilated by an artificial ventilator, comprising: a sensor for measuring the CO2 concentration in the expired gas during a single breath, an analog to digital converter for obtaining data samples of the CO2 concentration of the expired gas over a single breath in the time domain, means for selecting a plurality of data samples from said obtained data samples, means for calculating a mean tracing value being sensitive to changes of alveolar dead space on the basis of said selected data samples, and a data processor which detects during a change of the airway pressure of the artificial ventilator from the resulting course of a plurality of calculated mean tracing values the airway pressure level at which alveolar opening or lung overdistension or lung open condition or alveolar closing occurs."

IV. The arguments of the appellant can be summarised as follows:

The method defined in claim 1 according to the main request was not a method for treatment by therapy since the determination of the different significant airway pressure levels had no influence on the ongoing therapy and no specific illness was cured by the present method. The only aim of this method was to determine

relevant pressure levels in order to better control the ventilation applied to a patient, but the therapy pressure actually used during the course of the artificial respiration did not lie at these levels. A medical doctor would, during a regular artificial ventilation, not think of using as the therapy pressure levels the different relevant pressure levels determined by the claimed method.

There was no functional relationship between the method for determining the relevant pressure levels and the artificial ventilation just applied to the patient. The present case was in fact similar to that of T 245/87, in which it was considered that there was no functional link between the claimed flow measuring method and the therapeutical effect produced on the patient by the liquid medicament whose flow was measured.

Further, a similar method for testing the lungs of a patient was allowed by the Board in case T 1102/02.

In addition, it should be noted that no medical doctor was hampered by the present method as it was performed by a computer. Only a computer made it possible to calculate a mean tracing value from a large number of measured points and to determine therefrom the relevant slopes and thus the relevant pressure levels.

The present method could therefore not be considered to be or include a step in a method for treatment of the human body by therapy.

In claim 1 according to auxiliary request 1 the fact that the method was purely of a technical nature and executed by a computer was emphasised, so that the

objection that the claimed method could possibly be therapeutical was no longer relevant.

The claims of auxiliary request 2 were restricted to an apparatus for performing the previous method so that any objection under Article 53(c) EPC failed.

## **Reasons for the Decision**

1. The appeal is admissible.

### *Main request*

2. Method for treatment of the human body by therapy.

Pursuant to the transitional provisions relating to the Act revising the EPC of 29 November 2000 as decided by the Administrative Council on 28 June 2001, Article 53 applies to European patent applications pending at the time of its entry into force, and thus to the application under dispute in the present case.

- 2.1 Claim 1 refers to a method for determining airway pressure levels at which certain lung conditions of a lung ventilated by an artificial ventilator occur. The aim of the method is to determine the pressure levels at which alveolar opening or lung over distension or lung open condition or alveolar closing (hereinafter called relevant pressure levels) occur. The knowledge of these relevant pressure levels for an ailing lung is important to be able to determine the ventilator settings for the optimal, most efficient, ventilation of the patient and most efficient recruitment manoeuvre.

In essence the method consists of connecting the patient to the artificial ventilator, changing (increasing or decreasing) the airway pressure of the artificial ventilator step by step and for each of them calculating a plurality of mean tracing values being sensitive to changes in the dead space on the basis of a plurality of data samples of the CO<sub>2</sub> concentration of the expired gas over single breaths, from which the relevant pressure levels can be determined. This method is explained in details in the description of the patent application.

It is however immediately apparent that the above method requires the patient to be connected to the artificial ventilator in order to apply pressure to its lungs and to measure the concentration of CO<sub>2</sub> in the expired gas. It is also apparent that each pressure level applied to the lungs of the patient by the artificial ventilator when the airway pressure is changed according to the claimed method is not in any way superimposed on a "normal" ventilation pressure, but is the only pressure actually applied to the patient's lungs. In other words, the method is not applied on top of any normal artificial ventilation of the patient but during the ventilation phase in which the method is carried out it is the only artificial ventilation effectively applied to the patient. Therefore this, so to say, testing phase is just as vital for the survival of the patient than any other normal artificial ventilation.

It follows that the ventilation phase during which the method is executed cannot be distinguished from the normal artificial ventilation applied to the patient.



Further, the step of changing (increasing or decreasing) the airway pressure of the artificial ventilator in order to determine the relevant pressure levels cannot be distinguished from what a medical doctor would do in order to adapt an artificial ventilation to a given patient. As a matter of fact, the same parameter, namely the airway pressure, which is used to adapt or adjust a normal artificial ventilation to a given patient, is changed when the claimed method is carried out.

It is further to be noted that the claimed method cannot be considered as a momentarily short change of the ventilation parameters without any influence on the ongoing therapy. As a matter of fact, the claim defines neither any restrictive period of time for the measurements nor any specific intensity of the airway pressure changes. And according to the description of the specific embodiment (falling under the scope of the claim), in particular in relation to Figures 2 and 8, the detection phase extends over several tens of breaths, so that this period of time is clearly not insignificant but part of the ongoing therapy time.

Thus there is a functional and indissociable link between the claimed method and any artificial ventilation practised on a connected patient. It is indisputable that artificial ventilation is a therapeutic method because it aims at keeping the patient alive.

Whilst it is admitted that the primary intention of the appellant was not to protect a method for treatment but a method for determining the relevant pressure levels,

the Board is of the opinion that this is of little importance since the Enlarged Board has confirmed in G 1/07 (OJ EPO 2011, 134) that the presence of a single therapeutic or surgical step is sufficient to exclude the method from patentability:

*"... in the EPC revision the European legislator deliberately maintained the exclusions under Article 52(4) EPC 1973 in the now Article 53 c) EPC. Thereby the principle has been confirmed that medical and veterinary practitioners' freedom to use the best available treatments to the benefit of their patients uninhibited by any worry that some treatment might be covered by a patent is protected by excluding these activities from patentability. Excluding from patentability also multi-step methods which comprise or encompass a therapeutic or a surgical step serves to give full effect to that legislative purpose. Therefore, the principle developed in the jurisprudence that the presence of **one** therapeutic or surgical step in a multi-step method excludes that method from patentability is not only formally justified by the fact that the exclusion under Article 53 c) EPC does not contain any limitation as to the defined methods being excluded only when claimed as such. More importantly, it is also justified as to substance, i.e. it serves to enable achieving the legislative purpose served by the exclusion."*(emphasis added).

For the above reasons the Board considers that the claimed method falls under the exclusion of Article 53(c) EPC.

- 2.2 The appellant submitted that the present method did not cure any particular disease, and therefore did not

qualify as therapy. The Board does not share this opinion because, as already mentioned above, the present method cannot be distinguished from normal artificial ventilation, the very first aim of which is to keep an anaesthetised patient alive, which clearly must be considered as a therapeutic treatment since it avoids the death of the patient by artificially maintaining respiration.

The appellant further submitted that step e) introduced a malfunction in order to determine certain lung conditions. According to the wording of this feature, it requires changing the airway pressure of the ventilator and, as already mentioned above, such airway pressure changes belong to the normal activities of a doctor when adapting the ventilation conditions to the patient. Hence, any step by step increase or decrease of airway pressure when applying the method will necessarily merge with values used for the ventilation therapy itself. Therefore it is irrelevant whether the doctor uses the limit pressures levels for the ongoing therapy or not.

The appellant further submitted that case T 1102/02 should apply by analogy, the claimed method also being a test phase. The aim of the invention in that case was to determine the influence of the delivery tubing on the gas flow pattern delivered to the patient in order to correct the operating parameters of the artificial ventilator and to make sure that the gas flow pattern effectively delivered to the patient corresponded to the desired flow pattern, i.e. the aim was to optimise the flow of gas delivered by the delivery device. The present invention differs because it aims at detecting

relevant lung conditions of a particular patient for him to benefit most from the ongoing artificial ventilation. As previously mentioned, in the present invention the testing phase runs over tens of breathing cycles, as shown for example in Figures 2 or 8, so that the said phase cannot be distinguished from the normal artificial ventilation.

The appellant further submitted that a medical doctor would never be hampered by the claimed method as it was executed by a computer. The EPC excludes from patentability any methods of treatment by therapy in general. This has been confirmed by the Enlarged Board in G 1/07 point 3.2.3.2 *"...There is, however, no term in Article 53 c) EPC which would allow concluding that hampering of the practitioner's freedom is a prerequisite for the exclusion to apply in the individual case considered. The only condition defined in Article 53 c) EPC for a claim to be excluded from patentability is that it contains subject-matter being a method for treatment of the human or animal body by surgery or therapy or a diagnostic method. If so, it is excluded from patentability and it is then irrelevant whether in the individual situation under consideration a medical practitioner would or could infringe the claim."*

Finally the appellant submitted that the present case is comparable to that in T 245/87 (OJ EPO 1989, 171) and should therefore be allowed.

In case T 245/87 the method is for measuring the flow of liquid passing through a tubular element which can, among other things, belong to an implantable device for controlled drug administration. In order to measure the

flow rate, the electrical resistance of the flowing liquid is measured between two points. It is thus clear that the measuring method has no influence whatsoever on the flow rate per se with which the liquid is administered to the patient. The present method is quite different, since the airway pressure "administered" to the patient under artificial ventilation has to be changed in order to determine the relevant pressure levels. In the present method, again, an obvious functional link exists between the claimed method and the therapy applied to the patient.

*First auxiliary request*

3. In the first auxiliary request the appellant introduced the terms "in real time" and "automatically" in several features of claim 1 in order to emphasise that the method was executed by a computer.

In the opinion of the Board these amendments do not change the therapeutic nature of the claimed method as it is still carried out when the patient is connected and by changing the airway pressure applied to the patient's lungs.

Claim 1 according to the first auxiliary request thus also falls under the exception of Article 53(c) EPC.

*Second auxiliary request*

4. The second auxiliary request, however, comprises apparatus claims only, for which the exception of Article 53(c) EPC does not apply.

Since claims 1 to 20 according to the second auxiliary request correspond to originally filed claims 21 to 40, respectively, they also fulfil the requirements of Article 123(2) EPC.

*Remittal*

5. Since the objection upon which the impugned decision is based has been removed and the other requirements for grant have not yet been decided upon by the Examining Division, the Board considers that remittal of the case to the department of first instance for further prosecution pursuant to Article 111(1) EPC is appropriate.

**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 for further prosecution on the basis of the second auxiliary request filed during oral proceedings before the Board.

The Registrar:

The Chairman:

D. Sauter

M. Noël