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D E C I S I O N
of 17 January 2006

Case Number: T 0005/04 - 3.2.02

Application Number: 95941931.8

Publication Number: 0797403

IPC: A61B 5/00

Language of the proceedings: EN

Title of invention:

Internal registration of gas/air - and other fluid flows in a human body and use of pressure sensors for such registration

Applicant:

CAMTECH A.S.

Opponent:

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Headword:

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Relevant legal provisions:

EPC Art. 52(4), 123(2)

Keyword:

"Method comprising a surgical step"
"Extention of the claimed subject-matter"

Decisions cited:

T 0182/90, T 0775/97, T 0035/99

Catchword:

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Case Number: T 0005/04 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 17 January 2006

Appellant: CAMTECH A.S.
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Representative: Karlström, Lennart
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 7 August 2003
refusing European application No. 95941931.8
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. 95 941 931.8 (publication No. WO-A-96/18338) was refused by decision of the examining division dated 7 August 2003 on the ground that the method as claimed comprised a surgical step prohibited by Article 52(4) EPC.
- II. The appellant (applicant) lodged an appeal against this decision, by notice received on 7 October 2003 and paid the appeal fee on the same day. A statement setting out the grounds of appeal was filed on 8 December 2003 along with amended claims according to a main and a first auxiliary request.
- III. In consequence of a preliminary opinion of the Board communicated on 8 August 2005, the appellant replied by letter dated 3 January 2006 and filed an additional amended claim according to a second auxiliary request.

With his letter of 13 January 2006 the appellant informed the Board that he would not attend the oral proceedings scheduled to take place on 17 January 2006, and requested a decision on the basis of the present main and auxiliary requests.

In accordance with the provisions of Rule 71(2) EPC, the oral proceedings were held without the appellant.

- IV. Claim 1 according to the different requests reads as follows:

Main request:

"Method for internal registration and measurement of the respiratory flow and/or tidal volume in or out of a living body, wherein one or a series of sensors are placed at one or more points along the internal respiratory flow path, characterised in that the registration takes place through the utilisation of the sensor's or sensors' inherent temperature dependent properties, by means of the temperature and temperature difference in the respiratory fluid."

First auxiliary request:

"The use of one or more sensors for internal registration and measurement of the respiratory tidal volume through the utilisation of the sensor's or sensors' inherent temperature dependent properties, especially temperature and pressure sensors."

Second auxiliary request:

"A method for registration and measurement of the flow of a fluid, wherein one or a series of pressure sensors are located at one or more points along a flow path of the fluid, and the registration and measurement are permitted to take place through the utilization of the sensor's or sensors' inherent temperature dependent physical and electrical properties to measure the thermal variations in the flowing fluid."

V. In its written submissions the appellant presented the following arguments.

The method according to claim 1 of the main request did not claim the act of placing the pressure sensors inside the living body, but only the registration and measurement of the respiratory flow and/or tidal volume through the utilisation of the sensor's inherent temperature dependent properties. The sensors were already placed along the respiratory flow path of a patient. Moreover, this operation could not be regarded as a surgical step since no body tissues were penetrated. Article 52(4) EPC was to be construed narrowly and, therefore, not objectionable in this case.

The subject-matter of claim 1 according to the first auxiliary request related to the use of one or more sensors for a specific type of measurement, using the inherent, physical, thermal properties of the sensors in a new way. This was thus a matter of physics and not of physiology falling under the exclusion of Article 52(4) EPC.

The method claim according to the second auxiliary request was broadened in the way that the earlier references to respiratory flow and living body were deleted. This broadening was supported by the very last paragraph of the description as originally filed. The invention was not linked to any particular application, neither medical nor other applications. It was purely a technical matter based on how to take advantage of specific physical material properties within *per se* known pressure sensors in order to achieve both

pressure and thermal mass flow measurements, simultaneously.

Reasons for the Decision

1. The appeal is admissible.
2. *Main request*

The method according to claim 1 is designated as a "method for internal registration and measurement of the respiratory flow and/or tidal volume in or out of a living body, wherein one or a series of sensors are placed at one or more points along the internal respiratory flow path". The placing of sensors in one or more positions inside the respiratory airway of a patient by means of a flexible tube, as shown in Figure 1, implies a direct intervention on the living body.

For a method to be regarded as a method for surgical treatment and as such excluded from patentability under Article 52(4) EPC, it is not necessary that the intervention be invasive or that tissues be penetrated. The mere catheterisation or the insertion of components of a device into the body is already prohibited by Article 52(4) EPC as constituting a surgical step of the method (see T 35/99, OJ EPO 2000, 447). The time of placing the sensors, i.e. prior to the registration and measurement operation, is irrelevant in this respect and of no consequence on the above conclusion. What actually counts for the assessment of Article 52(4) EPC

is that the sensors are placed inside the body and that this feature is part of the method as claimed.

It results therefrom that the method as claimed involves at least one surgical step within the meaning of the case law of the boards of appeal (see also T 182/90, OJ EPO 1994, 641). Therefore, the subject-matter of claim 1 according to the main request is considered as a whole as a method for treatment by surgery excluded from patentability by Article 52(4) EPC.

3. *First auxiliary request*

Claim 1 according to the first auxiliary request relates to the "use of one or more sensors for internal registration and measurement of the respiratory tidal volume...", which also implies the insertion of the sensors into the respiratory flow path. Therefore, the alleged difference between the use of sensors for internal measurement of the respiratory tidal volume through the utilisation of the sensor's properties, according to the first auxiliary request, and a method for internal measurement of the respiratory tidal volume through the utilisation of the sensor's properties, according to the main request, is only a formal difference. Although these two requests are presented under different claim categories, both of them include implicitly or explicitly the same surgical step of placing the sensors into the respiratory air way.

In this respect, it matters little that the subject-matter of the use claim is more specifically focused on

the use of the known physical properties of the sensors, since a surgical step for inserting the sensors into the body is also implicitly required. The present situation is similar to the situation in case T 775/97 (unpublished) where a claim to the use of a device was refused because it implied the insertion of components of the device into a body (see point 2 of said decision).

As a result, the use claim according to the first auxiliary request does not meet the requirements of Article 52(4) EPC, either.

4. *Second auxiliary request*

The method according to the second auxiliary request differs from the method of the main request in that all references to the positioning of the sensors inside the body have been deleted, in order to overcome the objection under Article 52(4) EPC. However, said omission results in an extension of the claimed subject-matter which goes beyond the content of the application as filed.

The last paragraph of the description which is cited by the appellant as support for this amendment, states:

"This (temperature) effect has a high degree of stability, which means great advantages with a view to obtaining usable signals and registrations chiefly of respiration, but also registrations of other forms of gas and liquid flows."

In the Board's judgement the above paragraph is clearly inappropriate to support and justify the generalisation

of the method to registration and measurement of flows of fluid of any kind. Said paragraph which merely refers to potential uses of an effect must be construed in the context of the description as a whole. Since the patent application describes exclusively a method of registration and measurement of body fluids, in particular of breathing gas/air in the respiratory flow path of a patient (see a.o page 1, lines 1 to 21, page 4, lines 24 to 30; page 5, lines 6 to 11 and page 6, lines 21 to 27), there is no basis for departing from this specific context.

The subject-matter of the method claim according to the second auxiliary request, therefore, extends beyond the content of the application as filed contrary to the requirements of Article 123(2) EPC.

Although the appellant has not been previously informed about the reasoning to the second auxiliary request, this does not contravene Article 113(2) EPC, since the appellant did not attend the oral proceedings requested by himself and explicitly requested a decision on the basis of the present requests.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

T. Kriner