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D E C I S I O N
of 26 June 2006

Case Number: T 0238/06 - 3.2.02

Application Number: 03025749.7

Publication Number: 1386629

IPC: A61M 13/00

Language of the proceedings: EN

Title of invention:
Method for conditioning gas

Applicant:
Lexion Medical, LLC

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 52(4)

Keyword:
"Method excluded by Article 52(4) EPC (no) "

Decisions cited:
G 0001/04, T 0789/96, T 0245/87

Catchword:
-



Case Number: T 0238/06 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 26 June 2006

Appellant: Lexion Medical, LLC
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St. Paul, MN 55112-2750 (US)

Representative: Schäfer, Horst
Schweiger & Partner
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 6 October 2005
refusing European application No. 03025749.7
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: S. Chowdhury
E. Dufrasne

Summary of Facts and Submissions

- I. This appeal is against the decision of the examining division dated 6 October 2005 to refuse European patent application No. 03 025 749.7.

The ground of refusal was that the application did not meet the requirements of the EPC, the deficiencies having been set out in communications dated 29 September 2004 and 14 April 2005. The former made objections under Articles 52(4), 76(1), and Article 123(2) EPC, and Rule 29(2) EPC, while the latter elaborated on the Article 52(4) EPC objection only, and held that the claims then on file related to a therapeutic method performed on the human body, which fell under the exclusion of Article 52(4) EPC.

- II. On 5 December 2005 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee on the same day. On 3 February 2006 a statement of grounds of appeal was filed.

The appellant requests that the decision under appeal be set aside and that the application be remitted to the examining division for further prosecution on the basis of claims 1 to 12 of the main request or claims 1 to 10 of the auxiliary request filed by telefax on 16 May 2006.

- III. Independent claim 1 reads as follows:

"A method of treating gas (21) for use in an endoscopic procedure comprising the steps of:

- a) directing the gas (21) received from an insufflator (1) into the inlet of a chamber (6) having an inlet and an outlet and having a means for heating (20) the gas to a temperature within a predetermined range and a means for humidifying (28) the gas such that the gas can be heated and humidified simultaneously;
- b) sensing the temperature of the gas (23) as it exits the chamber (6) to determine if it is within the predetermined range; and
- c) actuating the heating means (20) if the temperature of the gas is without the predetermined range;
- d) humidifying the gas (28) within the chamber; and
- e) receiving the heated and humidified gas (27) at the predetermined temperature from the outlet of the chamber, thus treating the gas."

Reasons for the Decision

1. The appeal is admissible.
2. The decision under appeal appears to be based solely on Article 52(4) EPC, and it appears from the file that the examining division did not examine all substantive requirements for patentability. Hence if the appeal is allowed, it would be appropriate pursuant to Article 111(1) EPC to remit the case to the examining division for further prosecution.

Main request

3. *The application*

The application relates to a method of heating and humidifying insufflation gases prior to passage of the gases into the patient. The method can be utilized for medical procedures requiring the provision of heated and humidified gas, which gas is chosen according to the procedure, i.e. endoscopy, to be performed and can be any medically useful gas, such as carbon dioxide, oxygen, nitrous oxide, argon, helium, nitrogen and room air and other inert gases. The purpose of insufflating the patient with the gas is undoubtedly medical.

4. According to Article 52(4) EPC methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application.

4.1 Although the opinion of the Enlarged Board of Appeal G 1/04 relates to diagnostic methods only, it nevertheless indicates that Article 52(4) EPC is to be interpreted narrowly. The opinion concludes, inter alia, as follows:

1. 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.

(...)

3. In a diagnostic method under Article 52(4) EPC, the method steps of a technical nature belonging to the preceding steps which are constitutive for making the diagnosis for curative purposes *stricto sensu* must satisfy the criterion "practised on the human or animal body".

4. Article 52(4) EPC does not require a specific type and intensity of interaction with the human or animal body; a preceding step of a technical nature thus satisfies the criterion "practised on the human or animal body" if its performance implies any interaction with the human or animal body, necessitating the presence of the latter.

Thus, according to G 1/04 all method steps of a technical nature should satisfy the criterion "practised on the human or animal body", i.e. the performance of each and every one of these steps should imply an interaction with the human or animal body, necessitating the presence of the latter.

4.2 The presently claimed method is a method for treating a gas for use in an endoscopic procedure, ie prior to its passage to a patient. It contains method steps each of a purely technical nature, ie directing the gas into the inlet of a chamber, sensing the temperature of the gas, actuating heating means humidifying the gas, and receiving the heated and humidified gas at the predetermined temperature from the outlet of the chamber. Each of these steps is performed in a chamber independently of the patient to which the gas is passed, and not one of the steps requires any interaction with the patient necessitating the presence of same.

Therefore, the method cannot be considered as being "practised on the human or animal body".

4.3 The present situation is analogous to that of a method of controlling pulse parameters in a pacemaker (see Decision T 789/96, OJ 2002, 346), or a method of obtaining a correct flow rate of a composition for injection into the body (see Decision T 245/87, OJ 1989, 171), for example. If these methods involve purely technical steps and do not include any interaction with the body or the actual step of delivery of the pulse or the mixture to the body, they may be patentable under Article 52(4) EPC.

4.4 In the present case, were the step of flowing the gas into the patient to be included in claim 1, then the method would relate to a surgical method since the purpose of the gas is to inflate body cavities to create space for medical instruments, or a therapeutic

method (see EP-A-1 386 629, page 7, lines 51 to 53).
However, this final step is not included in claim 1.

5. For these reasons the claimed method is not to be considered a surgical or therapeutic method for the treatment of the human or animal body, which is excluded from patentability by Article 52(4) EPC.

Order

For these reasons it is decided that:

The case is remitted to the department of the first instance to resume the examination on the basis of claims 1 to 12 of the main request filed by telefax dated 16 May 2006.

The Registrar:

The Chairman:

V. Commare

T. K. H. Kriner