BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [X] To Chairmen
(D) [ ] No distribution

D E C I S I O N
of 23 May 2006

Case Number: T 0125/02 - 3.2.02

Application Number: 98124318.1

Publication Number: 0931506

IPC: A61B 5/083

Language of the proceedings: EN

Title of invention:
Evaluation of the respiratory function of a mammal

Applicant:
AEROCRINE AB

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 52(4)

Keyword:
"Diagnostic method practised on the human or animal body (yes)"

Decisions cited:
G 0001/04

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0125/02 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 23 May 2006

Appellant: AEROCRINE AB
Sundbybergsvägen 9
S-171 73 Solna (SE)

Representative: Holmberg, Martin Tor
Bergenstråhle & Lindvall AB
P.O. Box 17704
S-118 93 Stockholm (SE)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 25 July 2001 refusing European application No. 98124318.1 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. 98 124 318.1 filed as a divisional application to the earlier application No. 92 920 949.2 (international publication No. WO 93/05709) was refused by decision of the examining division dated 25 July 2001 on the grounds that the claimed subject-matter according to the main request then on file extended beyond the content of the earlier application (Article 76(1)) EPC and the method according to the auxiliary request then on file constituted a diagnostic method practised on the human or animal body (Article 52(4) EPC).

II. The appellant (applicant) lodged an appeal against this decision by notice received on 18 September 2001 and paid the appeal fee on the same day. A statement setting out the grounds of appeal was filed on 21 November 2001.

III. Oral proceedings were held on 23 May 2006 during which the appellant filed amended sets of claims according to a main request and three auxiliary requests.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 5 according to the main request, or claims 1 to 5 according to the first auxiliary request or of claim 1 according to the second or third auxiliary requests, all filed during the oral proceedings.

IV. Method claims 3 to 5 according to the main and the first auxiliary request read as follows:

"3. Method for ascertaining the current lung function of a human subject, characterized by the step of

- measuring the endogenous nitrogen monoxide content and/or the time-distribution of said endogenous nitrogen monoxide content during one or more exhalation phases in a sample of exhaled air.

4. Method according to claim 3, characterized in that it comprises the step of delivering nitrogen monoxide free air to the subject.

5. Method according to claim 4, characterized in that it further comprises the steps of

- comparing said measured content and/or time-distribution to the endogenous nitrogen monoxide content and/or the time-distribution of said endogenous nitrogen monoxide content during one or more exhalation phases of a human subject having complete or unimpaired respiratory tract function, and

- interpreting a deviation manifested by said comparison as an indication of impaired respiratory tract function."

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

"Method for ascertaining the current lung function of a human subject, characterized by the steps of

- delivering nitrogen monoxide free air to the subject,

- measuring the endogenous nitrogen monoxide content and/or the time-distribution of said endogenous nitrogen monoxide content during one or more exhalation phases in exhaled air,

- comparing said measured content and/or time-distribution to the endogenous nitrogen monoxide content and/or the time-distribution of said endogenous nitrogen monoxide content during one or more exhalation phases of a human subject having complete or unimpaired lung function, and

- interpreting a deviation manifested by said comparison as an indication of impaired lung function."

Claim 1 according to the third auxiliary request differs from claim 1 of the second auxiliary request by the deletion of the first step: "delivering nitrogen monoxide free air to the subject" from the method claim.

V. The applicant submitted that the amended claims filed at the oral proceedings defined intermediate steps only which did not make up a diagnostic method as defined in opinion G 1/04.

In particular, the last step of the method according to claim 5 of the main or the first auxiliary request, as well as the last step of the method according to claim 1 of the second or the third auxiliary request, which referred to "interpreting a deviation manifested by said comparison as an indication of impaired

respiratory tract (or lung) function", did not constitute a deductive medical or veterinary decision phase within the meaning of opinion G 1/04. Moreover, the method was not practised on the human or animal body. Instead, the analysis was performed on a sample of exhaled air removed from the body.

The method claim according to the third auxiliary request was further amended by deleting the step related to the delivery of air to the subject in order to render the method claim as less invasive as possible.

Reasons for the Decision

1. The appeal is admissible.

2. *Diagnostic method (Article 52(4) EPC)*

2.1 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."

This means that a diagnostic method in the sense of Article 52(4) EPC has to comprise the following steps (see G 1/04, point 5):

a) the examination phase involving the collection of data,

b) the comparison of these data with standard values,

c) the finding of any significant deviation, i.e. a symptom, during the comparison, and

d) the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase,

wherein the steps of a technical nature belonging to steps a) to c) must satisfy the criterion "practised on the human or animal body" (see headnote, point III).

As further specified in opinion G 1/04 under point 4 of the conclusion: "Artic1e 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".

2.2 In order to assess whether the present method is a diagnostic method according to Article 52(4) EPC it has to be evaluated whether or not the claimed method comprises the steps a) to d), and whether or not the steps of a technical nature out of steps a) to c) are practised on the human body.

a) The examination phase involving the collection of data.

The method under consideration according to all requests comprises the feature: "measuring the endogenous nitrogen monoxide content and/or the time distribution of said endogenous nitrogen monoxide content during one or more exhalation phases in a sample of exhaled air" (see claim 3 of the main and first auxiliary request and claim 1 of the second and third auxiliary request). This measuring clearly corresponds to an examination phase and inevitably involves the collection of data.

Since measuring is of a technical nature it has additionally to be evaluated whether or not it is practised on the human body.

It results from the feature "measuring... during one or more exhalation phases" that the presence of the human subject and its connection to the device is necessary even if the measuring was to be performed on exhaled air removed from the body. The condition "practised on the human body" is therefore satisfied in the present situation.

b) The comparison of these data with standard values.

In the method under consideration this step is represented by the feature: "comparing said measured content and/or time distribution to the endogenous nitrogen monoxide content and/or the time distribution of said endogenous nitrogen monoxide content during one or more exhalation phases of a human subject having complete or unimpaired lung function" (see claim 5 of the main and first auxiliary request and claim 1 of the second and third auxiliary request). This activity is predominantly of a non-technical nature.

c) The finding of any significant deviation, i.e. a symptom, during the comparison.

In the method under consideration, this step is represented by the feature: "(interpreting) a deviation manifested by said comparison" (see claim 5 of the main and first auxiliary request and claim 1 of the second and third auxiliary request). This step also has no technical character.

d) The attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase.

In the method under consideration, this step is represented by the feature: "interpreting (the deviation) as an indication of impaired respiratory tract (or lung) function" (see claim 5 of the main and first auxiliary request and claim 1 of the second and third auxiliary request).

This feature relates to the identification of a clinical picture as being the purpose set in the preamble of the claim (ascertaining the current lung function of a human subject). The objective of "ascertaining the current condition or function of a lung or lungs of a living subject" is constantly and repeatedly presented in the application as filed (see page 1, lines 7 to 10; page 3, lines 21 to 22 and 30 to 31; page 4, lines 4 to 5; page 7, lines 16 to 19; page 12, lines 21 to 25) as the main object of the present invention. The indication of an impaired lung function therefore represents the determination of the nature of a medical condition intended to identify or uncover a pathology or the negative finding that a particular condition can be ruled out, i.e. the diagnosis as defined under point 5.1 of the opinion G 1/04.

As actually mentioned in the application (see page 16, lines 16 to 20), the measurement of nitrogen monoxide produced in the lungs and respiratory tracts provides an understanding of the specific metabolic disorder in the lungs or along the respiratory tracts. The determination of the nature of this condition following the method, be it positive, negative or flat, is sufficient to decide upon the therapeutic action to be taken in response to the diagnosis in order to compensate or restore the condition or the function of the lung (see page 8, lines 1 to 19 and from page 12, line 27 to page 13, line 16). This action is actually considered as a treatment (see page 8, line 13 and page 13, line 10), which denotes the curative purpose of the diagnosis.

Consequently, the last step of the method can be regarded in the present context as the attribution of the deviation to a particular clinical picture, i.e. the deductive medical decision phase, i.e. the diagnosis referred to in opinion G 1/04.

3. It results therefrom that the method claim 5 according to the main and the first auxiliary requests as well as the method claim 1 according to the second and third auxiliary requests, which all contain the four steps identified above as steps a) to d), is a diagnostic methods practiced on the human body. Since patenting of such a method is prohibited by Article 52(4) EPC, the sets of claims according to the present requests must be refused.

4. The device claims presented in the main and the first auxiliary requests were not considered by the Board, for reasons of procedural efficiency, since the present application is in any case unallowable under Article 52(4) EPC with respect to the method claims which are present in all requests.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

V. Commare T. Kriner