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D E C I S I O N
of 27 June 2006

Case Number: T 0041/04 - 3.2.02

Application Number: 98914727.7

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IPC: A61B 5/00

Language of the proceedings: EN

Title of invention:

Method of assessing tissue viability using near-infrared spectroscopy

Applicant:

NATIONAL RESEARCH COUNCIL OF CANADA

Opponent:

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Headword:

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Relevant legal provisions:

EPC Art. 52(4)

Keyword:

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

Decisions cited:

-

Catchword:

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Case Number: T 0041/04 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 27 June 2006

Appellant: NATIONAL RESEARCH COUNCIL OF CANADA
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 22 July 2003
refusing European application No. 98914727.7
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: S. Chowdhury
A. Pignatelli

Summary of Facts and Submissions

- I. This appeal is against the decision of the examining division dated 22 July 2003 to refuse European patent application No. 98 914 727.7.

The ground of refusal was that the subject-matter of claim 1 constituted a diagnostic method within the meaning of Article 52(4) EPC.

- II. On 23 September 2003 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee on the same day. On 21 November 2003 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 6 (part) submitted with the grounds of appeal and claims 6 (remainder) to 10 filed by letter dated 7 June 2006.

- III. Independent claim 1 reads as follows:

"1. A non-invasive method of measuring total haemoglobin, oxygen saturation and hydration of a compromised tissue portion of a patient, the method comprising:
placing a visible and near-infrared emitting probe adjacent to a portion of tissue of the patient wherein the communication of fluids between the portion and a main body of the patient is compromised;
emitting visible and near-infrared light into the tissue portion;

collecting with the probe a spectrum of visible and near-infrared light from the tissue portion; analysing the spectrum to generate data related to deoxyhaemoglobin, oxyhaemoglobin and water content of the tissue portion; and determining the total haemoglobin, oxygen saturation and hydration of the tissue portion from said data, characterised in that the total haemoglobin, tissue oxygen saturation and hydration of the tissue portion can be determined from said spectrum."

Claims 2 to 10 are dependent claims.

Reasons for the Decision

1. The appeal is admissible.
2. *The application*

The application relates to a non-invasive method of measuring total haemoglobin, oxygen saturation and hydration of a compromised tissue portion of a patient which methods employ visible and near-IR spectroscopy, and was refused only on the basis of Article 52(4) EPC. Therefore, this will be the only point considered in this decision.

3. The Enlarged Boards of Appeal states in the opinion G 0001/04, inter alia, the following:

"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."

This means that a diagnostic method in the sense of Article 52(4) EPC must 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 a 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 the headnote, point III).

3.1 The presently claimed method may be performed on a human body, but the information which it yields provides only intermediate results by measuring at least one parameter of a sample during an examination phase (step a)). The claimed method does not include the comparison of this parameter with a standard value (step b)), or the finding of any significant deviation (a symptom) during the comparison (step c)), or the deductive medical or veterinary decision phase (step d)). Therefore, according to the Enlarged Board of Appeal, the claimed cannot be classified as a diagnostic method.

3.2 Therefore, the Board considers that the claimed method is not excluded from patentability by Article 52(4) EPC.

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 to resume the examination on the basis of claims 1 to 6 (part) submitted with the grounds of appeal and claims 6 (remainder) to 10 filed by letter dated 7 June 2006.

The Registrar

The Chairman

V. Commare

T. K. H. Kriner