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**Datasheet for the decision
of 19 October 2006**

Case Number: T 0990/03 - 3.4.01

Application Number: 99915902.3

Publication Number: 1070261

IPC: G01R 33/28

Language of the proceedings: EN

Title of invention:

Use of a hyperpolarized gas for MRI detection of regional variations in oxygen uptake from the lungs

Applicant:

Medi-Physics, Inc.

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 52(4), 111(1)

Keyword:

"Method of diagnosis (no)"

Decisions cited:

G 0001/04, G 0005/83

Catchword:

-



Case Number: T 0990/03 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 19 October 2006

Appellant: Medi-Physics, Inc.
101 Carnegie Center
Princeton, NJ 08540 (US)

Representative: Rollins, Anthony John
GE Healthcare Limited
Amersham Place
Little Chalfont
Bucks. HP7 9NA (GB)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 17 April 2003
refusing European application No. 99915902.3
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: B. Schachenmann
Members: G. Assi
H. Wolfrum

Summary of Facts and Submissions

- I. The appellant (applicant) lodged an appeal, received on 3 June 2003, against the decision of the examining division, dispatched on 17 April 2003, refusing European patent application No. 99915902.3 (publication number 1 070 261). The fee for the appeal was paid on 3 June 2003. The statement setting out the grounds of appeal was received on 15 August 2003.
- II. In the contested decision, the examining division held that the claimed methods according to the requests then on file constituted diagnostic methods practised on the human or animal body and thus were excluded from patentability pursuant to Article 52(4) EPC.
- III. Oral proceedings before the Board were held on 19 October 2006.
- IV. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the following documents:

Claims:

Nos. 1-21 filed on 19 September 2006 as main request,

Description:

Pages 1-14, 17-31 of the published application,
Pages 15, 16 filed in the oral proceedings on
19 October 2006,

Drawings:

Sheets 1/13-13/13 of the published application.

V. The wording of claims 1 and 21 reads as follows:

"1. A method of detecting regional variations in oxygen uptake from the lungs of an air-breathing animal subject, said method comprising administering into the lungs of said subject a diagnostically effective amount of a gaseous hyperpolarized magnetic resonance imaging agent, detecting the magnetic resonance signal from said agent in said lungs, and characterised in that by determining the temporal variation in relaxation rate for said signal for at least one region of interest within said lungs, a qualitative or quantitative value or image indicative of the oxygen concentration in said at least one region of interest is generated from said variation, and if desired the time dependency of such concentration."

"21. Use of a magnetic resonance active nuclei-containing material for the preparation of a gaseous hyperpolarized magnetic resonance imaging agent for use in a method of treatment or diagnosis involving performance of the method as described in any one of claims 1 to 20."

Claims 2-20 are dependent claims.

Reasons for the Decision

1. The appeal is admissible.

2. *Diagnostic method*

2.1 The Enlarged Board of Appeal held in the opinion G 1/04 (OJ EPO 2006, 334) that the principle, according to which exclusion clauses from patentability laid down in the EPC were to be construed in a restrictive manner, did not apply without exception. However, the Enlarged Board of Appeal considered that the principle of a narrow interpretation of such exclusion clauses was to apply in respect of the scope of the exclusion from patentability under Article 52(4) EPC concerning diagnostic methods (see Reasons, No. 6, last paragraph).

With this understanding, the Enlarged Board held that there was no reason to deviate from the established jurisprudence of the EPO, according to which the method steps to be carried out when making a diagnosis as part of the medical treatment of humans or the veterinary treatment of animals for curative purposes included (see Reasons, No. 5):

- (i) the examination phase involving the collection of data,
- (ii) the comparison of these data with standard values,
- (iii) the finding of any significant deviation, i.e. a symptom, during the comparison, and
- (iv) the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase (*diagnosis stricto sensu*).

Thus, in order that the subject-matter of a claim relating to a diagnostic method practised on the human or animal body fell under the prohibition of

Article 52(4) EPC, the claim was to include the feature pertaining to the diagnosis *stricto sensu* (see (iv)), as well as the features relating to the preceding steps which were constitutive for making the diagnosis (see (i), (ii) and (iii)), and the specific interactions with the human or animal body which occurred when carrying those out among said preceding steps which were of a technical nature. In other words, with regard to the preceding steps, those which were of a technical nature had to meet the criterion "*practised on the human or animal body*" (see Reasons, No. 8).

2.2 The present application relates to a method of detecting regional variations in oxygen uptake from the lungs of an air-breathing animal subject. The method according to claim 1 includes the following steps:

- (a) administering into the lungs of the subject a diagnostically effective amount of a gaseous hyperpolarized magnetic resonance imaging agent,
- (b) detecting a magnetic resonance signal from the agent in the lungs,
- (c) determining the temporal variation in relaxation rate for the signal for at least one region of interest within the lungs,
- (d) generating from said variation a qualitative or quantitative value or image indicative of the oxygen concentration in said at least one region of interest and, if desired, the time dependency of such concentration.

2.3 Step (a) represents a preceding step which is constitutive for collecting data. It may be regarded as being of a technical nature since it implies the use of

an application unit (see the published description, page 12, lines 25-37). Moreover, the step requires an interaction with, or is practised on, the human or animal body, the presence of which is thus necessary.

Steps (b), (c) and (d) correspond to the examination phase (i) involving the acquisition of raw data represented by the detected magnetic resonance signal (see (b)) as well as data processing so as to obtain information concerning the temporal variation in relaxation rate for the signal (see (c)) and the qualitative or quantitative value or image (see (d)).

Thus, the claimed method does not comprise the comparison of the collected data with standard values (see (ii)), the finding of any significant deviation (see (iii)), and the attribution of the deviation to a particular clinical picture (see (iv)). It results that, in the light of G 1/04, the claimed method does not concern a diagnostic method, but at best a method of data acquisition or data processing that may be used in a diagnostic method. In particular, the final data provided by the method, i.e. a qualitative or quantitative value or image, represent intermediate findings of diagnostic relevance, which must not be confounded with the diagnosis for curative purposes *stricto sensu* (see G 1/04, Reasons, No. 6.2.2, second sentence; No. 6.2.3, third sentence from the end). This conclusion is supported by the wording of claim 21 which makes clear that diagnosis involves performance of the method of claim 1.

2.4 In conclusion, the method of claim 1 does not have a diagnostic character.

3. *Further prosecution*

3.1 During the first instance procedure, the examining division only addressed the issue of exclusion from patentability pursuant to Article 52(4) EPC.

In the decision under appeal, this issue was comprehensively analysed with regard to diagnostic methods practised on the human or animal body. The exclusion of methods for treatment of the human or animal body by surgery was also considered in the appealed decision but not thoroughly; indeed, it is dealt with in a single sentence (see Reasons, No. 5.3) which may be regarded as having the character of an *obiter dictum*.

3.2 Therefore, the Board limited itself to the examination of the diagnostic issue.

The case is remitted to the first instance for further prosecution (Article 111(1) EPC, second sentence, second alternative). In particular, the exclusion from patentability pursuant to Article 52(4) EPC other than of diagnostic methods and the further provisions of the EPC need to be examined.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the examining division for further prosecution on the basis of the following documents:

Claims:

Nos. 1-21 filed on 19 September 2006 as main request,

Description:

Pages 1-14, 17-31 of the published application,
Pages 15, 16 filed in the oral proceedings on
19 October 2006,

Drawings:

Sheets 1/13-13/13 of the published application.

The Registrar:

The Chairman:

A. Vottner

B. Schachenmann