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D E C I S I O N
of 12 July 2006

Case Number: T 1197/02 - 3.2.02

Application Number: 95917232.1

Publication Number: 0758862

IPC: A61B 3/024

Language of the proceedings: EN

Title of invention:

Method and apparatus for early detection of glaucoma

Applicant:

THE AUSTRALIAN NATIONAL UNIVERSITY

Headword:

-

Relevant legal provisions:

EPC Art. 84, 52(4), 123(2)

Keyword:

"Diagnostic method (yes)"

"Apparatus formally acceptable (after amendments)"

Decisions cited:

G 0001/04

Catchword:

In a claim concerning a diagnostic method, only the steps strictly describing the examination phase involving the collection of data, the comparison of these data with standard values, the finding of any significant deviation and the attribution to a clinical picture have to be taken into account for determining the diagnostic character of the claimed method.

Additional, intermediate, preparatory steps which may be introduced into the claimed method are irrelevant when assessing the diagnostic character of the method. It is therefore not necessary that these additional steps which are of a technical nature or are using technical means, fulfil the criterion "practised on the human or animal body" (see point 2.2).



Case Number: T 1197/02 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 12 July 2006

Appellant: THE AUSTRALIAN NATIONAL UNIVERSITY
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Representative: Ede, Eric
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 6 June 2002
refusing European application No. 95917232.1
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 (Publication No 0 758 862) was refused by decision of the examining division dated 6 June 2002 on the grounds that claims 1 to 5 related to a diagnostic method performed on the human body, which fell under the exclusion of Article 52(4) EPC, and lacked inventive step under Article 56 EPC vis à vis the state of the art. Further, apparatus claim 6 lacked clarity under Article 84 EPC.
- II. The appellant (applicant) lodged an appeal against the decision on 6 August 2002 and paid the appeal fee on the same day. A statement of grounds of appeal was filed on 16 October 2002 along with amended sets of claims.
- III. In response to a communication of the Board, the appellant submitted, by letter dated 12 June 2006, new sets of claims according to a main request and five auxiliary requests.
- IV. Oral proceedings were held on 12 July 2006 in the course of which the fifth auxiliary request was amended.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or the auxiliary requests one to four all filed with letter of 12 June 2006, with the corrections in the main and the second auxiliary requests filed with letter of 6 July 2006 and in the fourth auxiliary request filed on 10 July 2006, or on the basis of the fifth auxiliary request filed at the oral proceedings.

V. The method claim 1 according to the main request reads:

"A method of assessing the presence of glaucomatous damage to the visual system of a subject, the method comprising steps of:

- (a) generating and displaying a pattern having characteristics consistent with observing a spatial frequency-doubled illusion obtained by a contrast-modulated grating pattern;
- (b) presenting said pattern within the visual field of view of a subject;
- (c) measuring a contrast threshold value at which said subject can just discern each pattern while fixating on a fixation spot wherein said fixation spot is located at 0° azimuth and elevation in said visual field;
- (d) performing two or more repeats of step (c);

characterized in that said visual field of view is divided into a plurality of zones, wherein said zones include at least the entire or a selected portion of the superior peripheral visual field, the inferior peripheral visual field, and the combined superior and inferior peripheral visual fields; and

- (e) presenting said pattern to a subject within each of the zones sequentially;
- (f) calculating the mean of the logarithm of the threshold values to determine the zone which produces the highest threshold value,
- (g) ranking the threshold values; and
- (h) comparing the maximally ranked threshold value with a standard value based on subjects of normal vision."

VI. The apparatus claim 1 according to the fifth auxiliary request reads:

"An apparatus for assessing the presence of glaucomatous damage to the visual system of a subject, comprising:

a display system adapted to present a pattern within the visual field of view of a subject, said pattern having characteristics consistent with observing a spatial frequency-doubled illusion obtained by a contrast-modulated grating pattern;

means to adjust the contrast of the pattern to include a measurable contrast threshold value at which the subject can just discern said spatial frequency-doubled illusion pattern while fixating on a fixating spot located at 0° azimuth and elevation in said visual field of view;

characterised in that the display system includes means to mask the pattern into regions such that any part of the display system which is not covered by the pattern is held at the mean luminance of the pattern, whereby the display system divides the visual field of view into a plurality of zones, wherein said zones include at least the entire or a selected portion of the superior peripheral visual field, the inferior peripheral visual field, and the combined superior and inferior peripheral visual fields, and wherein said display system presents the pattern to a subject within each of the zones sequentially; and

means to calculate the mean of the logarithm of the measured threshold values to determine the zone which produces the highest threshold; and means to compare said threshold with a standard value based on subjects having normal vision."

VII. At the oral proceedings the appellant submitted that in claim 1 according to the main request, at least step (a) of generating and displaying a pattern having peculiar characteristics, step (f) of calculating the mean of the logarithm of the threshold values to determine the zone which produces the highest threshold value and step (g) of ranking the threshold values, were of a technical nature, but not practised on the human body in the sense that the presence of the body was not required.

Since, as specified under point 3 of the conclusion and point 6.4.4 in the opinion G 1/04 all method steps which were of a technical nature had also to satisfy the criteria "practised on the human or animal body", the present method, therefore, was not prohibited by Article 52(4) EPC.

The apparatus claim 1 according to the fifth auxiliary request contained a combination of structural and functional features for performing the method and the specification that the display system was operated in order to divide the visual field of view into a plurality of zones. All these features contributed to better distinguish the apparatus from those of the prior art and were fairly supported within the content of the application as filed, in compliance with Article 123(2) EPC.

Reasons for the Decision

1. The appeal is admissible.

2. *Method claims (Article 52(4) EPC)*

2.1 In its opinion G 1/04 (OJ EPO 2006, 334) the Enlarged Board of Appeal stated, 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.

2. [...]

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."

More specifically, as also results from the point 5 in the opinion G 1/04, those preceding steps which are constitutive for making the diagnosis are:

- a) the examination phase involving the collection of data,
- b) the comparison of these data with standard values, and
- c) the finding of any significant deviation, i.e. a symptom, during the comparison, ...

2.2 The criterion "practised on the human or animal body" is to be considered only in respect of method steps which are of a technical nature (points 6.4.1 and 6.4.4 of G 1/04). Thus it neither applies to the deductive decision phase, nor to the above mentioned steps b) and c) which consist in comparing the data collected in the examination phase with standard values and in finding a significant deviation resulting from the comparison. These activities are principally of a non-technical nature and normally not practised on the human or animal body.

It results therefrom that in most cases only step a) which refers to the examination phase and involves the collection of data can actually be of a technical nature and, therefore, concerned with the criterion "practised on the human or animal body".

Additional, intermediate steps which concern for example the adjustment or preparation of the apparatus with which the collection of data will be performed may be introduced into a method claim for completeness. However, since these additional features are not part of one of the steps a) to c) mentioned above, which are necessary for making the diagnosis, they are to be ignored when assessing the diagnostic character of the method. The issue of whether or not these intermediate features are of a technical nature and practised on the human or animal body is, therefore, irrelevant for this question. Thus, contrary to the appellant's submission, it is not correct to require that all the steps pertaining to a claim to a diagnostic method, which are of a technical nature or are using technical means, fulfil the criterion "practised on the human or animal body" in order to exclude the method from patentability.

- 2.3 In the present method claim 1 according to the main request, the steps identified (a) to (e) are all claimed as part of the examination phase for collecting data by sequentially measuring contrast thresholds values in a plurality of previously determined zones which are presented successively to the visual field of the subject to be tested. However, step (a) which relates to generating and displaying a pattern having suitable characteristics has to be regarded as an

additional step within the meaning of section 2.2 above, and, consequently, can be left aside when determining the diagnostic character of the claimed method. The remaining steps ((b), (c), (d), (e)) are of technical nature and require the presence of the subject for observing the patterns.

The step (h) represents the comparison of the collected thresholds with standard values exhibited by subjects of normal vision and, implicitly, the finding of any significant deviation resulting from the comparison, i.e. the symptom. These activities are not technical by nature and, therefore, need not be practised on the human body.

Intermediate steps (f) and (g) of calculating the mean of the logarithm of the threshold values to determine the zone which produces the highest threshold value and ranking the threshold values, respectively, represent a preliminary processing, with computing means, of the data collected in steps (a) to (e), in order to make a valid and efficient comparison with standard values. Although they are of a technical nature, these intermediate steps are not part of the comparison per se and thus are of no relevance for making the diagnosis. As a consequence, they are not to be considered, for the question whether or not the claim refers to a diagnostic method in the sense of Article 52(4) EPC.

The deductive medical decision phase, i.e. the diagnosis for curative purposes *stricto sensu*, is easily identified at the beginning of claim 1 by the

provision of "a method of assessing the presence of glaucomatous damage to the visual system of a subject".

It results therefrom that the method claim 1 according to the main request includes all the features of a diagnostic method practised on the human or animal body as defined in the opinion G 1/04. Such a method is prohibited by Article 52(4) EPC.

- 2.4 The amendments made to the method claims according to the first to fourth auxiliary requests, by addition or deletion of features, do not change the above conclusion since the diagnosis, i.e. the deductive medical decision phase, and all the preceding steps which are constitutive for making the diagnosis, including the interaction with the human body during the data collection phase, are still present in all the method claims according to these requests.

Therefore the subject-matter of all these method claims also define a diagnostic method within the meaning of the opinion G 1/04 and are excluded from the patentability by Article 52(4) EPC. Consequently the main request and the auxiliary requests 1 to 4 are not allowable.

3. *Apparatus claims (Article 123(2) EPC).*

With respect to the application as filed the claims to the apparatus according to the fifth auxiliary request were amended as follows:

3.1 Claim 1

The features of the preamble of claim 1 are based on the features of the original claim 8, supplemented by features drawn up from the description as filed, see page 3, lines 22-24, page 4, lines 25-26 and page 9, lines 29-30.

A further specification of the modulation frequency range of the contrast is deemed not to be necessary since the technique and frequencies to be applied for observing a frequency-doubled pattern of the grating is well known from the closest prior art document D7 (US-A-5065767).

The features of the characterising portion of claim 1 are based on the features of original claims 10 and 9, respectively, supplemented by features taken from the description as filed, see page 9, lines 7-9. The selected zones are shown in Figures 1(b) and 1(d). The means for masking the pattern are supported by the paragraph on page 10, lines 14-17. A sequential presentation of the pattern and subsequent determination of the threshold values is supported by the passage on page 9, lines 26-29.

3.2 Dependent claims 2 to 6

The features of claim 10 are based on features from the original claim 10.

The features of claim 11 are supported by the description as filed, page 10, lines 22-27.

The features of claims 12 and 13 are based on the features of original claims 11 and 12, respectively.

The features of claim 14 are supported by the description as filed, page 5, lines 10-14.

- 3.3 It results therefrom that all the amendments made to the apparatus claims are clear and supported by the application as filed. Moreover, their subject-matter does not extend beyond the content of the application as filed, in agreement with the requirements of Article 123(2) EPC. Therefore, the apparatus claims according to the fifth auxiliary request are formally acceptable.

4. *Remittal*

Since the claims at issue, now restricted to the apparatus for performing the method, were greatly modified, in particular by the incorporation of features (means to mask the pattern) possibly not having been searched, the Board finds it appropriate to remit the case to the examining division for further prosecution on the substantive issues on the basis of claims 1 to 6 of the fifth auxiliary request filed at the oral proceedings.

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 for further prosecution on the basis of the fifth auxiliary request.

The Registrar

The Chairman

V. Commare

T. Kriner