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D E C I S I O N
of 21 September 1999

Case Number: T 0966/97 - 3.4.2

Application Number: 87311516.6

Publication Number: 0273768

IPC: G01N 25/18

Language of the proceedings: EN

Title of invention:

Method to quantify thermal dissipative mechanisms in biomaterials

Applicant:

Bowmann, Harry Frederick, et al

Opponent:

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Headword:

-

Relevant legal provisions:

EPC Art. 84, 54, 56

Keyword:

"Clarity of the claims (yes, after amendment)"
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:

-

Catchword:

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Boards of Appeal

Chambres de recours

Case Number: T 0966/97 - 3.4.2

D E C I S I O N
of the Technical Board of Appeal 3.4.2
of 21 September 1999

Appellant:

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Decision under appeal:

Decision of the Examining Division of the
European Patent Office posted 15 April 1997
refusing European patent application
No. 87 311 516.6 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: E. Turrini
Members: A. G. Klein
M. Lewenton

Summary of Facts and Submissions

- I. European patent application No. 87 311 516.6 (publication No. 0 273 768) was refused by decision of the Examining Division, on the ground that the subject-matter of claim 1 was not clear within the meaning of Article 84 EPC.

The Examining Division in particular held that claim 1 did not clearly define the essential method steps of the iterative calculation performed for computing the thermal properties, nor all the method steps needed for achieving the objective of avoiding any measurements under no-flow conditions (see paragraph 1.6 of the Reasons). The Examining Division further held that there was no single inventive concept linking together the subject-matter of independent claims 1 and 11 (Article 82 EPC) and that the subject-matter of independent claim 11 lacked an inventive step within the meaning of Article 56 EPC in view of the contents of documents:

D2: Journal of Biomechanical Engineering vol. 106, August 1984, pages 192 to 197; J. W. Valvano et al.: "The Simultaneous Measurement of Thermal Conductivity, Thermal Diffusivity, and Perfusion in Small Volumes of Tissue".

The remaining documents cited in the European Search Report are:

D1: US-A-4 059 982;

D3: Journal of the National Cancer Institute vol. 60,

Monograph 61, 1982, pages 437 to 445;

H. F. Bowman: "Heat Transfer Mechanisms and Thermal Dosimetry";

D4: US-A-4 522 512; and

D5: Annual Review of Biophysics and Bioengineering vol. 4, 1975, pages 43 to 80; H. F. Bowman et al.; "Theory, Measurement, and Application of Thermal Properties of Biomaterials".

II. The appellants (applicants) filed an appeal against the decision rejecting the application.

With their statement of grounds they filed an amended independent claim 1 and an amended claim 11 appended to claim 1, in replacement of the independent claims 1 and 11 on which the rejection was based. In the statement of the grounds of appeal they submitted that claim 1 as amended was now clearly directed to a method comprising an iteration step, in which intrinsic conductivity and/or diffusivity were calculated in a time period where there was flow and the thermal transfer effects of flow were relatively low, perfusion being calculated as a function of the result of said conductivity/diffusivity calculating step, and of changes in the temperature and power as occurred in a second time period when the thermal transfer effects of flow were greater.

The objections raised against independent claim 11 in the appealed decision no longer applied since the claim had been appended to claim 1.

III. The Board informed the appellants in a communication of its provisional opinion that the claims and description still gave rise to certain objections, as set out in the communication, which called for further, essentially formal amendments.

IV. In response to the communication of the Board, the appellants filed an amended set of claims 1 to 19, together with amended pages 1, 5, 5a, 7, 7a, 9 and 27 of the description.

As their main request, they requested that the decision under appeal be set aside and, implicitly, that a patent be granted on the basis of the newly filed claims and pages of the description, together with the remaining pages of the description and drawings already on file.

Claim 1, the only independent claim of the set of claims in accordance with the main request, reads as follows:

"1. A method for determining, under flow conditions, the perfusion in a medium having a fluid flowing in the medium comprising: locating a thermal probe in the medium; applying power to the probe to create a temperature difference between the probe and the medium thereby to heat the medium; and monitoring the power supplied to the probe and the temperature change of the probe,

characterised by calculating the intrinsic thermal conductivity and/or diffusivity of the medium as a function of the changes in temperature and power in a first time period when the thermal transfer effects of

flow in the medium are low and the conductivity of the medium dominates as a factor effecting thermal transfer; and

calculating the perfusion as a function of the intrinsic conductivity and/or diffusivity calculated in the previous step and the changes in temperature and power in a second time period, subsequent to the said first time period, when the thermal transfer effects of flow upon the probe are greater than the thermal transfer effects of flow upon the probe during the first time period."

In the event that dismissal of the appeal was contemplated, the appellants requested that oral proceedings be summoned (auxiliary request).

Reasons for the Decision

1. The appeal meets the requirements of Articles 106 to 108 and of Rule 64 EPC. It is admissible, accordingly.
2. The amended application documents do not in the Board's opinion offend against the provisions of Article 123(2) EPC.

In particular, claim 1 corresponds in substance to independent claim 17 as filed, with the further limitations that the calculated intrinsic thermal property of the medium, as referred to in original claim 17, is specified to be intrinsic thermal conductivity and/or diffusivity, whilst the data used for the calculation, as generally defined in original claim 17 are specified as being changes in temperature

and power, as was described in the second paragraph of page 8 of the description as originally filed.

The fact that the claimed method is performed "under flow conditions" was emphasised e.g. in the first sentence of the Brief Summary Of The Invention on page 7 of the description as originally filed.

The extrapolation technique, the iterative calculation until convergence, the temperature cycle, the selection of the first and second time periods defined in dependent claims 2 to 6 were disclosed originally in conjunction with Figures 1 and 2 (see the description page 19, second paragraph to page 26, first paragraph).

The immersing of a cooling means in the medium in accordance with claim 7 was set out also in claim 7 as originally filed. The method with the specific algorithms as set out in claims 8, 9 and 11 to 17 correspond in substance to the methods of claims 8 to 16 as originally filed. The use of a thermistor bead as set out in claim 10 was disclosed in the fourth paragraph on page 10 of the description as originally filed.

The method of claims 18 and 19, which involves the calculating of a plurality of thermal conductivity and/or thermal diffusivity values and their extrapolating, with the assumed value of perfusion being substantially zero, was disclosed originally in conjunction with Figure 2 (see in particular the two first paragraphs on page 23 as originally filed).

Finally, the description was amended only for

adaptation to the claims as amended, and supplemented with a short summary of the relevant content of document D2, in agreement with the requirements of Rule 27(1)(c) and (b) EPC, respectively.

3. *Clarity*

3.1 The invention relates to a method for determining the perfusion of a fluid through a medium (e.g. the flow of blood through a tumour) under flow conditions, i.e. without interrupting the flow, by monitoring the power supplied to a probe located in the medium and the resulting change in temperature of the probe (see the first full paragraph on page 8 of the description).

The crux of the invention is the idea of performing a first measurement at an early stage of the heating cycle, when perfusion does not yet much contribute to the heat transfer, so as to calculate values of the thermal conductivity or diffusivity of the medium which are close to the "intrinsic" value (i.e. the value under no-flow conditions). These values are then used together with the values derived from a second measurement performed at a later stage, when the effect of perfusion is more pronounced, to calculate the true perfusion.

3.2 Present claim 1 in the Board's opinion now adequately defines the above method, and in particular the two-step process consisting first in "calculating the intrinsic thermal conductivity and/or diffusivity of the medium as a function of the changes in temperature and power in a first time period when the thermal transfer effects of flow in the medium are low and the

conductivity of the medium dominates as a factor effecting thermal transfer", followed by the second step of "calculating the perfusion as a function of the intrinsic conductivity and/or diffusivity calculated in the previous step and the changes in temperature and power in a second time period, subsequent to the said first time period, when the thermal transfer effects of flow upon the probe are greater than the thermal transfer effects of flow upon the probe during the first time period".

The claim is also correctly drafted in the two-part form recommended under Rule 29(1) EPC, in view of the nearest prior art disclosed in document D2 (see hereunder).

4. *Patentability*

The documents on the file, in particular the citations of the European Search Report, which in the Board's opinion are correctly assigned to the "A" category as disclosing technological background only, do not anticipate the claimed method, neither do they render it obvious to a person skilled in the art.

In particular, document D2 is the sole citation to teach the deriving of the value of perfusion directly from the effective conductivity and diffusivity of a medium as measured under flow conditions, and it thus constitutes the nearest prior art as set out in the preamble of claim 1. In the method of document D2, however, the value of the effective perfusion is obtained by a different iterative calculation from a measurement of the transient voltage response required

to maintain a volume average temperature increment as applied to the medium (see the steps quoted 1 to 9 in the left-hand column of page 194). This known method neither involves, nor suggests the two-step process set out in the characterising portion of present claim 1.

In this respect, the Board notices that in the examining procedure both the appellants and the Examining Division considered that the method of document D2 required interruption of flow. Flow interruption is however disclosed in the document in conjunction with the operation of an experimental arrangement, using an isolated rat liver preparation as shown in Figure 4 of page 195, only to evaluate the proposed perfusion quantifying method, which itself actually operates under flow conditions (see in particular the first and the second paragraphs of the "Conclusions" on page 197).

The method disclosed in document D1 for the determination of perfusion explicitly requires that the intrinsic thermal properties of the medium be first determined under no-flow conditions (see e.g. all the claims directed to the determination of the rate of flow like claims 10, 13, 16, 28, 30 and 32).

Document D3 merely shows results of calculations of perfusion as derived in a non-specified manner from effective thermal conductivity, without hinting at the claimed two-step procedure (see Figures 9 to 11).

Document D4 relates to the determining of the bulk thermal conductivity of a particular material, which does not involve any perfusion effects.

Document D5 generally relates to the measurement of thermal properties of biomaterials. It does not describe any details of a method of determining tissue perfusion. Quite on the contrary, the document states that "despite the accumulation of valuable work in this area, tissue perfusion has not been derived from thermal properties" (see page 72, first paragraph).

For the above reasons the subject-matter of claim 1 is considered to be novel and inventive within the meaning of Articles 54 and 56 EPC.

The same conclusion applies to the subject-matter of claims 2 to 19, by virtue of their appendence to claim 1.

5. The patent application and the invention to which it relates in the Board's view also meet the remaining conditions of the Convention.

In particular, the objections put forward by the Examining Division in the appealed decision against the subject-matter of then independent claim 11 under Articles 82 (lack of unity) and 56 EPC (lack of inventive step) no longer apply to present claim 11, which is now appended to claim 1.

The description has also been adequately adapted to the wording of independent claim 1, and supplemented with a short summary of the relevant content of the nearest prior art as constituted by the method of document D2.

The appellants' main request can therefore be allowed.

The appellants' auxiliary request for oral proceedings need not be considered further, accordingly.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to grant a patent as follows:

Claims: 1 to 19 as filed with the appellants' letter dated 1 June 1999;

Description: pages 2 to 4, 6, 8 and 10 to 26 as originally filed;
pages 1, 5, 5a, 7, 7a, 9 and 27 as filed with the appellants' letter dated 1 June 1999;

Drawings: page 1/1 as originally filed

The Registrar:

The Chairman:

P. Martorana

E. Turrini