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**Datasheet for the decision
of 25 May 2007**

Case Number: T 1070/05 - 3.2.02

Application Number: 97203072.0

Publication Number: 0908137

IPC: A61B 8/12

Language of the proceedings: EN

Title of invention:

A method and apparatus for making an image of a lumen or other body cavity and its surrounding tissue

Applicant:

Volcano Corporation

Opponent:

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Headword:

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Relevant legal provisions:

EPC Art. 52(1), 56

Keyword:

"Inventive step (yes, after amendment)"

Decisions cited:

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Catchword:

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Case Number: T 1070/05 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 25 May 2007

Appellant: Volcano Corporation
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Representative: Smulders, Theodorus A.H.J.
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 16 March 2005
refusing European application No. 97203072.0
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: S. Chowdhury
E. Dufrasne

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division posted on 16 March 2005 to refuse European patent application No. 97 203 072.0.

The application was refused on the grounds of Articles 52(1) and 56 EPC, because the subject-matter of claim 1 lacked an inventive step having regard to document D1 (WO-A-94/23652).

II. On 19 May 2005 the appellant lodged an appeal against the decision and paid the prescribed fee on the same day. On 22 July 2005 a statement of grounds of appeal was filed.

III. Oral proceedings took place on 25 May 2007. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of:

- Claims 1 to 9 filed at the oral proceedings;
- description pages 1, 1a, 2, 3, 4 filed at the oral proceedings and pages 5 to 13 as originally filed;
- figures 1 to 6 as published.

IV. Independent claim 1 reads as follows:

"Apparatus for making an image of a lumen or other body cavity and its surrounding tissue in a body comprising a transducer arranged for insertion in the lumen or cavity and for emitting ultrasound signals to be directed towards a wall of said lumen or cavity, and for collecting echo signals, and comprising processing means arranged for processing echo signals in a manner

known per se for ultrasound techniques to form an image of the lumen or cavity and its surrounding tissue, and to derive information related to the stiffness of the tissue around the lumen or the cavity from the emitted and collected signals, which information can be displayed in the image that has been formed, said transducer further arranged to:

- a) after insertion of the transducer in a lumen or cavity surrounded by its tissue, obtain one or more echo signals from tissue in a chosen direction, said tissue assumed to be at a given state of mechanical stress; and to
- b) obtain one or more echo signals from said tissue in said chosen direction, after the given state of mechanical stress has changed; said processing means further arranged, in response to receiving said echo signals from said transducer, to
- c) determine the extent of the lumen or the cavity in said chosen direction in order to identify the lumen-tissue boundary or the cavity-tissue boundary;
- d) compare the echo signals from steps a) and b) starting at the lumen-tissue boundary or the cavity-tissue boundary and for a finite depth in the tissue to obtain a parameter indicative of tissue stiffness of the inner layer of tissue in said chosen direction;
- e) simultaneously or successively or intermittently perform the steps a) to d) for a number of directions;
- f) derive and display the conventional echo image of the cavity or lumen and its surrounding tissue from the echo signals obtained in step a); and to
- g) superimpose in the image obtained in step f) the parameter indicative of the tissue stiffness, characterized in that the processing means is further arranged to present said parameter as a coded line

along the inner surface of tissue at the lumen-tissue or cavity-tissue boundary thereby not disturbing presentation of the echo image and to identify regions of increased strain on the said coded line."

V. Claims 2 to 9 are dependent claims.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

The preamble of claim 1 is based on claim 8 as originally filed. The characterising part of claim 1 is supported by paragraphs [0013], [0030], and [0031], so that the claim as a whole is fairly based on the application as originally filed (EP-A-0 908 137).

The apparatus is characterised by purely functional features which, however, the person skilled in the art would be able to carry out without undue burden, so that no objection arises in this respect.

3. *Inventive step*

3.1 The nearest prior art document is D1, which discloses apparatus for making an image of a lumen or other body cavity and its surrounding tissue in a body, having all the features of the preamble of claim 1. This fact was acknowledged by the appellant during the appeal procedure and is correctly reflected in the two-part formulation of the claim having regard to D1.

- 3.2 Starting from D1 the technical problem is to identify regions of increased strain, for example caused by plaque being deposited on the inner wall of an artery.

This is achieved by presenting the parameter as a coded line along the inner surface of tissue at the lumen tissue or cavity tissue boundary thereby not disturbing presentation of the echo image and to identify regions of increased strain on the said coded line.

- 3.3 It was explained by the appellant at the oral proceedings that the occurrence of strain is a local effect arising adjacent the lumen-tissue boundary, where plaque tends to deposit, and that increased strain occurs around the edges of the plaque.

The combination of the coded line displayed as close as possible to the image of lumen but without disturbing it, makes it possible to interpret the image accurately, and to highlight regions of increases strain on the image.

- 3.4 In D1 it is the averaged deformation of the tissue which is measured along the radial directions of scan. (see D1, page 5, feature (i)). The averaging step causes local information to be lost, so that regions of increased strain, for example localised at the inner surface of a lumen, cannot be identified.

Moreover, the coded line 33 of D1 is somewhat remote from the inner surface of the lumen, which detracts from accuracy of image interpretation.

The apparatus of D1 is not only incapable of performing the functions set out in the characterising part of claim 1, but it also does not suggest that localised strain information may be obtained and identified by a combination of a coded line and an image of the lumen.

There is no other cited state of the art which would suggest the characterising features of claim 1, and the claim involves an inventive step, 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 on the basis of:
 - Claims 1 to 9 filed at the oral proceedings;
 - description pages 1, 1a, 2, 3, 4 filed at the oral proceedings and pages 5 to 13 as originally filed;
 - figures 1 to 6 as published.

The Registrar

The Chairman

V. Commare

T. K. H. Kriner