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D E C I S I O N
of 15 January 2002

Case Number: T 0773/99 - 3.2.2

Application Number: 92925231.0

Publication Number: 0611292

IPC: A61B 8/12

Language of the proceedings: EN

Title of invention:

Transvascular ultrasound hemodynamic catheter and method

Applicant:

MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 52(1), 54

Keyword:

"Novelty (no)"

Decisions cited:

-

Catchword:

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Boards of Appeal

Chambres de recours

Case Number: T 0773/99 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 15 January 2002

Appellant: MAYO FOUNDATION FOR MEDICAL
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 22 February 1999
refusing European patent application
No. 92 925 231.0 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: W. D. Weiß
Members: S. S. Chowdhury
R. T. Menapace

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 22 February 1999 to refuse European patent application No. 92 925 231.0

There were three grounds of refusal, two of which concerned amendments to the description, and the third was that, having regard to document D2 (WO-A-90 13260), the subject-matter of independent claim 1 lacked novelty.

The examining division argued that the description had not been amended satisfactorily to meet objections raised under Article 84 and Rule 34(1)(b) EPC, and document D2 disclosed all the features of claim 1 of the application, including a phased array ultrasonic transducer, so that the subject-matter of this claim lacked novelty.

II. On 22 April 1999 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee at the same time. On 22 June 1999 a statement of grounds of appeal was filed.

III. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the following documents:

- Claims 1 to 7 filed with the letter dated 6 May 1998.
- Description pages 5, 6, and 11 to 21 as originally filed.

- Description pages 2, 2b and 7 to 10 filed with the letter dated 19 August 1996.
- Description pages 1 and 2a filed with the letter dated 23 May 1997.
- Description pages 3 and 4 filed with the letter dated 6 May 1998.
- Drawing sheets 1/6 to 6/6 as originally filed.

IV. Independent claim 1 of this request reads as follows:

1. "A catheter apparatus, comprising: an elongated body (22) having proximal and distal ends (24, 26); a phased array ultrasonic transducer (30) mounted proximate the distal end (26) of the elongated body (22) to transmit ultrasound and receive resultant echoes so as to provide a field of view within which features can be imaged; a port (40) being directed such that the port is capable of delivering a device into the field of view; and an electrical conductor for electrically connecting the transducer to control circuitry of the catheter."

Claims 2 to 7 are dependent on claim 1.

V. With respect to novelty of the subject-matter of claim 1 the appellant argues as follows:

Document D2 emphasised that a combination of fibre optics and ultrasonic means in a single instrument was provided for the purpose of enabling direct visualisation via the fibre optics and determination of blood flow velocity and direction via the ultrasonic

means. The latter were not used to visualise down the tube.

Nowhere did document D2 disclose or teach a catheter apparatus having a phased array ultrasonic transducer to provide a field of view within which features could be imaged. The ultrasonic monitoring means of document D2 did not provide direct visualisation, it was the fibre optic means that provided the visualisation.

The reference on page 12 of document D2 to obtaining a two-dimensional image was misleading and, in the context, could only be interpreted as being a reference to obtaining a two-dimensional image of the blood flow velocity and direction.

Document D2 disclosed an embodiment in which a fibre optical bundle was connected to a video coupler to produce an image on a video monitor. If the ultrasound means did indeed provide an image of the field of view, there would be no need of such a video monitor.

Document D2 taught away from the use of a phased array ultrasonic transducer which provided an image in a field of view in that it stated that the invention of D2 was the combination of ultrasound operations with fibre optic direct visualisation in a single instrument.

Reasons for the Decision

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

Document D2, with reference to Figure 6 thereof, describes a catheter apparatus comprising an elongated body having proximal and distal ends 14, 16; a phased array ultrasonic transducer 26 (see point 3.1 below) mounted proximate the distal end 16 of the elongated body to transmit ultrasound and receive resultant echoes so as to provide a field of view within which features can be imaged (see point 3.1 below); a port being directed such that the port is capable of delivering a device into the field of view (see point 4 below); and an electrical conductor for electrically connecting the transducer to control circuitry of the catheter (page 14, lines 9 to 13).

Therefore, document D2 discloses the combination of all the features of claim 1 such that the catheter apparatus defined in the claim lacks novelty.

- 2.1. The appellant's arguments regarding the disclosure of document D2, in point V of the Summary of Facts, have not impressed the Board for the following reasons:
 - 2.1.1 The passages of the description of document D2 on page 12, line 9 to page 13, line 29 provide a clear and unambiguous teaching of the use of a phased array ultrasonic transducer mounted proximate the distal end of the catheter to provide an image of the area adjacent the catheter tip. The paragraph linking pages 11 and 12 describes the apparatus in its simplest form, and comprises a fibre optic viewer and a piezoelectric crystal for determining Doppler shifts. An alternative version, however, described in the paragraph commencing at line 9 on page 12, describes the use of a piezoelectric crystal for B-mode imaging, which is a well known ultrasonic imaging operation.

In another embodiment (see the paragraph linking pages 12 and 13) focussing and steering of the beam for imaging is performed by a commercially available phased array ultrasonic transducer, and in yet a further refinement a coloured blood flow representation is superimposed on a gray scale B-mode image of the blood vessel (page 13, lines 13 to 16). This is an explicit mention of imaging the internal vascular structure by the ultrasonic means.

These features are also provided in the specific embodiment described with respect to Figure 6, as described on pages 18 and 19.

2.1.2 While document D2 might emphasise the importance of the combination of fibre optics and ultrasonic means in a single instrument for the purpose of enabling direct visualisation via the fibre optics and determination of blood flow velocity and direction via the ultrasonic means, this does not preclude the inclusion of further means in the combination as further refinements. In particular the addition of ultrasonic imaging means is not precluded from the combination.

The optical fibres are used to place the catheter at the correct anatomical site (page 7, lines 18 to 21), whereas the ultrasonic means are used to image structures outside the vascular system, as in the present application (see the application page 15, lines 9 to 16). Thus, the provision of ultrasonic means for imaging in document D2 as well as fibre optics is not a redundant measure. Nor does it contradict the statement in this document that the fibre optics are used to provide direct visualisation, or the statement that the essence of the invention of

document D2 is the a combination of fibre optics and ultrasonic means in a single instrument.

- 2.2 Concerning the feature that the port of the catheter of document D2 is capable of delivering a device into the field of view, there are references in this document to the passage of an electrically conducting wire or a laser beam for cauterisation, on page 14, lines 20 to 27, and claims 11 and 12, for example. These may be considered as "devices" in the sense of claim 1 of the application, which covers the same devices, see page 14 of the application, under the section "Intervention".
- 2.3 For the above reasons the subject-matter of claim 1 of the application is anticipated by document D2 and the claim does not meet the novelty requirements of Article 52(1) EPC.
3. In view of this finding the Board does not propose to rule on the other grounds of refusal.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß