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D E C I S I O N
of 7 December 2004

Case Number: T 0918/03 - 3.2.2

Application Number: 94303387.8

Publication Number: 0624346

IPC: A61B 17/34

Language of the proceedings: EN

Title of invention:
Blunt tipped ultrasonic trocar

Applicant:
ETHICON, INC.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
"Novelty and inventive step (yes, after amendments)"

Decisions cited:
-

Catchword:
-



Case Number: T 0918/03 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 7 December 2004

Appellant: ETHICON, INC.
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Representative: Fisher, Adrian John
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 10 April 2003
refusing European application No. 94303387.8
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: T. K. H. Kriner
Members: D. Valle
U. J. Tronser

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal on 20 May 2003 against the decision of the examining division, posted on 10 April 2003, refusing the European patent application No. 94 303 387.8. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 12 August 2003.

II. The examining division held that the application did not meet the requirements of Article 54 EPC having regard to the following document:

D7 = US-A-4 870 953.

III. In addition to this document, the following documents cited in the search report, in the description, or during the examining proceedings have been considered for the present decision:

D1 = DE-A-37 07 921

D2 = WO-A-92/14514

D3s = US-A-5 151 084

D4s = DE-A-29 22 239

D5s = EP-A-0 495 634

D3 = CA-A-1 098 003

D4 = US-A-5 180 363

D5 = US-A-5 123 903

D6 = WO-A-92/11 815.

IV. Following a request of the appellant, oral proceedings took place on 7 December 2004.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of:

- Claims:

1 to 31, as submitted at the oral proceedings;

- Description:

pages 1 to 16 as submitted at the oral proceedings;

- Figures:

1, 3 to 9 and 11 to 16 as filed with letter of 12 July 1994;

2 and 10 as filed with letter of 10 September 2002.

V. Claim 1 reads as follows:

"An obturator assembly (10) comprising:

a cannula (14) comprising a cannula handle (17) and a cannula tube (18) extending from said cannula handle (17);

an obturator (12) for puncturing tissue to access a location for endoscopic surgery, said obturator being insertable through said cannula for obturating said cannula, and said obturator comprising:

an ultrasonic transducer (21);

a solid blunt puncturing tip (24);

a shaft (23) having a proximal end coupled to said transducer (21) and a distal end coupled to said tip (24);

means for supplying electrical energy to the transducer (21) to cause the transducer (21) to vibrate at a frequency of 20 to 150 kHz and propagate vibrations along the shaft (23) to the tip (24) thereby causing the tip (24) to vibrate at an amplitude of 10 to 300 microns;

a feedback mechanism for determining variations in the load on the tip caused by differences in acoustical impedance of tissue; and

control means (63) for controlling the energy supplied to the transducer (21) based on feedback from said feedback mechanism."

VI. In support of his request, the appellant relied essentially on the following submissions:

D7 was not suitable to represent the most relevant state of the art, since it did not belong to the field of the invention. D2, which was much more relevant, failed in particular to disclose a feedback mechanism for determining variations in the load on the puncturing tip caused by differences in acoustical impedance of tissue. No document of the available prior art contained a hint toward this feature and therefore the subject-matter of claim 1 should be considered as novel and involving an inventive step.

Reasons for the Decision

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

The present claims have the following support in the original disclosure:

Claim 1:	claim 6, page 3, lines 13 to 20, page 4, lines 16 to 25, page 12, third paragraph
claims 2, 3:	page 7, first paragraph
claim 4:	claim 1
claims 5, 6:	page 7, second paragraph
claim 7:	page 7, first paragraph
claim 8:	page 16, second paragraph
claim 9:	page 15, third paragraph
claims 10 to 14:	claims 8 to 13
claim 15:	page 7, fourth paragraph
claims 16 to 20:	claims 14 to 18
claim 21:	paragraph bridging pages 12 and 13
claim 22:	page 11, second paragraph
claim 23:	page 11, third paragraph
claim 24:	Figure 16
claim 25:	page 8, second paragraph, claim 2
claims 26, 27:	claims 3, 4
claim 28:	page 8, second paragraph
claim 29:	claim 5
claim 30:	page 8, first paragraph
claim 31:	page 10, second paragraph.

The amendments to the description have been made in order to evaluate the most relevant documents of the state of the art and to adapt the description to the new claims. The drawings have been amended to correct some clerical errors.

3. *Novelty*

3.1 D7 discloses an apparatus comprising a catheter with a catheter handle (see Figure 1), a catheter tube (8) extending from said catheter handle and a probe (6), said probe being insertable through said catheter, and comprising an ultrasonic transducer (20), a solid blunt tip (44), a shaft having a proximal end coupled to said transducer and a distal end coupled to said tip and means for supplying electrical energy to the transducer to cause the transducer to vibrate at a frequency of 20 to 27 kHz and propagate vibrations along the shaft to the tip thereby causing the tip to vibrate at an amplitude of 40 microns.

However, D7 does not disclose that the apparatus is an obturator assembly, that the catheter is a cannula, that the probe is an obturator for puncturing tissue to access a location for endoscopic surgery, that a feedback mechanism is provided for determining variations in the load on the tip caused by differences in acoustical impedance of tissue and that a control means is provided for controlling the energy supplied to the transducer based on feedback from said feedback mechanism.

3.2 D2 discloses an obturator assembly comprising a cannula (32) comprising a cannula handle and a cannula tube extending from said cannula handle (see Figure 1), an obturator (36) for puncturing tissue to access a location for endoscopic surgery, said obturator being insertable through said cannula for obturating said cannula, and said obturator comprising: an ultrasonic transducer (inevitably comprised in an ultrasonic device as described on page 15, paragraph 1, and therefore implicitly disclosed in D2), a solid blunt puncturing tip (see for example Figure 1), an element (conductor) having a proximal end coupled to said transducer and a distal end coupled to said tip, means for supplying electrical energy to the transducer to cause the transducer to vibrate at a frequency of 20 to 150 kHz (100 to 1200 kHz, see page 15, paragraph 1) and propagate vibrations along the element to the tip, a feedback mechanism, and control means for controlling the energy supplied to the transducer based on feedback from said feedback mechanism (see claims 1 and 4).

However, D2 does not disclose that the element connecting the transducer with the tip is a shaft, that the tip vibrates at an amplitude of 10 to 300 microns; and that the feedback mechanism is designed for determining variations in the load on the tip caused by differences in acoustical impedance of tissue.

3.3 The further documents of the available prior art are less relevant. D1, D3s, D4s, D5s, D3 and D5 do not disclose a feedback mechanism. D4 does not disclose an obturator but a surgical device in the field of orthopaedic, ophthalmology or dental surgery. D6 does not disclose an obturator but a device for angioplasty.

3.4 Accordingly claim 1 is novel.

4. *Inventive step*

4.1 D7 does not represent the most relevant state of the art for the following reasons:

The device according to the invention is an improvement of the traditional trocar, where the obturator is manually pressed through the trocar, the skin and the underlying tissues in order to open a passage for an endoscope. Typically this method is applied in abdominal surgery.

The device according to D7 is however a catheter to be inserted in blood vessels, containing a vibrating probe designed to remove intravascular blockage due to atherosclerosis or blood clot. Such a probe is neither designed, nor suitable for creating a passage through the skin or other tissues.

4.2 The most relevant state of the art is disclosed in D2 which, like the present application, refers to an obturator assembly comprising an obturator for puncturing tissue to access a location for endoscope surgery. Starting from D2, the object underlying the present application may be regarded as reducing the risk of injury to soft or underlying tissue by puncturing the outer layers of tissue by means of the obturator (see page 2, second paragraph of the present application).

This object is achieved among other things by the feature according to which the feedback mechanism is designed for determining variations in the load on the tip caused by differences in acoustical impedance of tissue. This feedback mechanism allows to determine when the vibrating tip has perforated a certain tissue layer.

Since the available prior art does not suggest the provision of such a special feedback mechanism, the obturator assembly according to claim 1 cannot be regarded as being obvious.

- 4.3 Accordingly the subject-matter of claim 1 involves also an inventive step.

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 31 as submitted at the oral proceedings on 7 December 2004;
 - description:
pages 1 to 16 as submitted at the oral proceedings on 7 December 2004;

- Figures:

1, 3 to 9 and 11 to 16 as filed with letter
of 12 July 1994;

2 and 10 as filed with letter of
10 September 2002.

The Registrar:

The Chairman:

V. Commare

T. Kriner