

Internal distribution code:

- (A) Publication in OJ
(B) To Chairmen and Members
(C) To Chairmen
(D) No distribution

D E C I S I O N
of 15 September 2004

Case Number: T 0718/03 - 3.2.2

Application Number: 96910913.1

Publication Number: 0821568

IPC: A61B 8/12

Language of the proceedings: EN

Title of invention:

A method and an apparatus for the insertion of a needle guide into a patient in order to remove tissue samples

Applicant:

B & K Ultrasound Systems A/S

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 54, 56, 123(2)

Keyword:

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

Decisions cited:

-

Catchword:

-



Case Number: T 0718/03 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 15 September 2004

Appellant:

B & K Ultrasound Systems A/S
Sandtoften 9
DK-2820 Gentofte (DK)

Representative:

Siiger, Joergen
c/o Chas. Hude
H.C. Andersens Boulevard 33
DK-1553 Copenhagen V (DK)

Decision under appeal:

Decision of the Examining Division of the
European Patent Office posted 20 February 2003
refusing the European application No.
96910913.1 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: T. K. H. Kriner
Members: D. Valle
E. J. Dufrasne

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal against the decision of the examining division, posted on 20 February 2003, refusing the European patent application No. 96 910 913.2. The notice of appeal and the statement setting out the grounds for appeal were received on 10 April 2003, and the fee for the appeal was paid simultaneously.

II. The examining division held that the application did not meet the requirements of Article 52(1) EPC in conjunction with Article 54 EPC, having regard to the document:

D1 = US-A-4 763 662.

III. In addition to the above document, the following documents, cited in the search report and in the description of the application, have been considered for the present decision:

D2: US-A-5 256 149

D3: US-A-4 911 173.

D4: US-A-4 605 009.

IV. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the following version of the application:

- Claims: No. 1 to 3 filed with facsimile of
2 September 2004;

- Description: Pages 1, 2a, 3 to 7 filed with
letter of 1 July 2004;

Page 2 filed with letter of
19 September 2002;

- Drawings: Figures 1 to 5 filed with facsimile
of 9 September 2004.

V. Claim 1 reads as follows:

"An apparatus for ultrasonic guided removal of tissue samples (biopsies), comprising a catheter carrying an ultrasonic transducer (8) at its end, and a mounting member for mounting of a needle guide (2) with a needle to the ultrasonic transducer (8) for insertion of the needle in the image plane of the ultrasonic transducer (8) which is associated with a display for imaging of the needle, said needle guide (2) being predominantly flexible, but rigid at the end at the mounting member and is inclined with a permanent angle to a longitudinal axis of the catheter, characterised in that the mounting member for mounting of the needle guide (2) to the ultrasonic transducer (8) is clipped onto the catheter adjacent the transducer (8) so that the needle guide (2) is inclined with said permanent angle to the longitudinal axis of the catheter, said needle guide (2) being placed along the catheter with the ultrasonic transducer (8) in such a manner that said needle guide (2) together with the transducer (8) can be inserted through a trocar."

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

D1 disclosed a guide sheath (32) pivotally secured to the transducer and not - like the invention - removably clipped onto the catheter adjacent the transducer. The guide sheath connection of D1 required a fixed channel (26) which was difficult to clean and disinfect.

Since the state of the art did not suggest the provision of a mounting member and needle guide as defined in the characterising part of claim 1, the subject-matter of the present claims was new and involved an inventive step.

Reasons for the Decision

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

The subject-matter of claim 1 is disclosed in claim 1, in the description, page 6, last paragraph, and in Figures 8a to 11 of the published application (WO-A-96/32889). The subject-matter of claim 2 is disclosed in claim 8 and in the description, page 7, lines 10 to 14 of WO-A-96/32889, and the subject-matter of claim 3 is disclosed in the published claims 9 and 10. The description and drawings have been adapted to the newly filed claims.

Consequently, the amendments to the application meet the requirements of Article 123(2) EPC.

3. *Novelty*

3.1 D1 discloses an apparatus (endoscope) for ultrasonic guided removal of tissue samples (biopsies), comprising a catheter (tubular insertion section 12) carrying an ultrasonic transducer (28) at its end and a mounting member for mounting of a needle guide (32) with a needle (52) to the ultrasonic transducer, for insertion of the needle in the image plane of the ultrasonic transducer which is associated with a display for imaging of the needle, said needle guide being predominantly flexible, but rigid at the end at the mounting member and is inclined at a permanent angle to a longitudinal axis of the catheter (see Figures 8 to 12).

However, D1 does not disclose that the mounting member for mounting of the needle guide to the ultrasonic transducer is clipped onto the catheter adjacent to the transducer so that the needle guide is inclined with said permanent angle to the longitudinal axis of the catheter, and that said needle guide is placed along the catheter with the ultrasonic transducer in such a manner that said needle guide together with the transducer can be inserted through a trocar.

3.2 D2 refers to a trocar with a transparent cannula and not to an apparatus for ultrasonic guided removal of tissue samples (biopsies).

3.3 D3 discloses a biopsy attachment (90, see Figures 3, 4) for ultrasound probe of the rectal area where the probe is partially inserted in the body through the sphincter.

The external part of the attachment (90) shows a releasable mounting member for the needle guide (106, see Figures 3 to 7) with a movable leg (96) which can be extended in order to position the needle for the biopsy.

However, D3 does not disclose that the apparatus is designed to be inserted through a trocar, nor that the needle guide is inclined with a permanent angle to the longitudinal axis of the catheter, nor that the mounting member is clipped to the transducer.

3.4 D4 refers to an ultrasonic sweep echography and display endoscopic probe and not to an apparatus for ultrasonic guided removal of tissue samples.

4. *Inventive step*

4.1 The most relevant state of the art is disclosed in D1.

Starting from this document, the object underlying the present application may be regarded as to provide a flexible system, capable to withstand a bending of a relatively small radius (see description of the patent application, page 2a, lines 8 and 9) and to improve the possibility to clean and disinfect the apparatus.

4.2 This object is achieved by the provision of a catheter wherein the needle guide is fixed to the transducer by means of a mounting member which is clipped onto the catheter adjacent to the transducer so that the needle guide is inclined with a permanent angle to the longitudinal axis of the catheter, and wherein the needle guide is placed along the catheter in such a

manner that said needle guide together with the transducer can be inserted through a trocar.

The fact that the needle guide is placed along the catheter makes the system more flexible, whereas the releasable mounting member in the form of a clip improves the possibility to clean the apparatus.

- 4.3 Neither D1 alone, nor a combination of the teaching of D1 with any other document of the available prior art can lead the skilled person in the field in an obvious way to the claimed invention, since none of the available documents discloses or hints at a needle guide arranged along the catheter and mounted with clipping means onto the catheter.

5. Therefore, the subject-matter of the present claims is novel and involves an inventive step.

