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D E C I S I O N
of 22 September 2004

Case Number: T 0964/03 - 3.2.2

Application Number: 97926339.9

Publication Number: 0921829

IPC: A61M 5/32

Language of the proceedings: EN

Title of invention:
Protection for puncture needles

Applicant:
Wiklund, Ernst Sigurd Gustaf Folke

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 54

Keyword:
"Novelty (yes, after amendments)"

Decisions cited:
-

Catchword:
-



Case Number: T 0964/03 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 22 September 2004

Appellant: Wiklund, Ernst Sigurd Gustaf Folke
Lindevägen 40
S-120 48 Enskede Gård (SE)

Representative: -

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 11 April 2003
refusing European application No. 97926339.9
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 11 April 2003, refusing the European patent application No. 97 926 339.9. The notice of appeal was filed on 5 June 2003, the statement setting out the grounds for appeal was received on 10 August 2003, and the fee for the appeal was paid on 28 May 2003.

II. The examining division held that the application did not meet the requirements of Article 52(1) EPC in conjunction with Article 54 EPC, since the subject-matter of claim 2 then on file was not novel with respect to:

D2: US-A-5 536 257.

Furthermore, the examining division held that the subject-matter of claims 3 to 5 did not involve an inventive step.

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

D1: WO-A-91/01154

D3: US-A-5 460 611

D4: EP-A-0 405 039

D5: EP-A-0 657 184

D6: EP-A-0 356 810

D7: US-A-5 312 345.

The document US-A-5 536 587 cited at page 2, second line from the bottom of the description of the application, obviously does not concern the subject-matter of the present application and therefore it will not be considered further.

- 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:

Nos. 1 to 10 filed with facsimile of 13 September 2004;

Description:

Pages 1 to 24 filed with letter of 25 February 2003;

Drawings:

Figures 1 to 54 published in WO-A-97/45152.

- V. Independent claim 2 reads as follows:

"Puncture needles and cannulae intended for tissue penetration comprising a needle body and provided with a point protector comprising a thin-walled internal or external tube (or hose) closely fitted to the needle and combined with a protector tube body, when the protector tube is surrounding the needle, or a stiffened elongation, when the protector tube is inside

the needle characterised by a protector tube body (2.2) or a stiffened elongation (2.4) of the protector tube (2.0) designed to interact with the needle body (1.2) to mechanically push the protector tube (2.0) forward over the needle from a non-active rest position to an active protective position with its front end (2.1) some millimetres in front of the needle point (1.1), where it is fixed irreversibly, at which the activation can be done latest at the stage, when the needle is drawn out."

Claim 1 is directed to a method for preventing blood infections at the use of hypodermic puncture needles comprising the step of using a device as defined in claim 2.

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

The point protector disclosed in D2 did not comprise a thin-walled tube closely fitted to the needle. A close fit between the thin-walled tube and the needle eliminated the most serious drawbacks of the protector according to the first and third alternatives in D2, i.e. that the protector at the handling after activation might be deformed and the protector sheath might be exposed to penetration forces applied perpendicularly to the surface.

Therefore the subject-matter of claim 1 was novel and involved an inventive step.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

The subject-matter of claims 1 and 2 is disclosed in claims 1 and 2, in the description, page 3, lines 27 to 31, page 4, lines 3 to 5, page 7, lines 29 to 33, page 7, last line to page 8, line 3, Figures 1 to 7 and 14 of WO-A-97/45152. The features of claims 3 to 6, 9 and 10 are disclosed in claims 3 to 6, 10 and 11, respectively, of WO-A-97/45152. Claim 7 is supported by claims 7 and 8 of WO-A-97/45152. Claim 8 is supported by the passage of the description at page 19, lines 19 to 30 and by Figure 44 of WO-A-97/45152.

Consequently, the present claims meet the requirements of Article 123(2) EPC.

3. *Novelty*

3.1 D2 discloses (see in particular Figures 1A to 2B) a puncture needle (5) and cannulae intended for tissue penetration comprising a needle body (4) and provided with a point protector comprising a thin walled external tube (6) combined with a protector tube body (7), whereby the protector tube body is designed to interact with the needle body to mechanically push the protector tube forward over the needle from a non-active rest position (see Figure 1A) to an active protective position (see Figure 2A) with its front end some millimetres in front of the needle point where it is fixed irreversibly (by the interaction of the

elements 9 and 10, see Figure 2B), at which the activation can be done latest at the stage when the needle is drawn out.

Contrary to the contention of the appellant, the board is convinced that the walls of the tube 6 of D2 are thin, in particular when compared with the overall size of the tube itself.

However, D2 does not disclose that that the protector tube is closely fitted to the needle.

Accordingly, the subject-matter of claim 2 is novel over D2. The same conclusion applies to method claim 1, since it contains the same distinguishing feature.

3.2 The further documents are less relevant than D2.

D1 discloses puncture needles (15) and cannulae intended for tissue penetration comprising a needle body and provided with a point protector comprising a thin-walled external tube (19) closely fitted to the needle and combined with a protector tube body (26). However, D1 does not disclose that the protector tube body is designed to interact with the needle body to mechanically push the protector tube forward over the needle from a non-active rest position to an active protective position with its front end some millimetres in front of the needle point where it is fixed irreversibly, at which the activation can be done latest at the stage, when the needle is drawn out.

D3 discloses an external protector tube (111, see Figure 1) closely fitted to the needle, but not

combined with a protector tube body, like the invention.

D4 does not disclose a protector tube closely fitted to the needle.

D5 does not disclose a thin-walled internal tube but a rod (12, see Figure 1).

D6 discloses a protector tube body (21, 22, 23, 30; see Figure 2) which however does not interact with the needle body, but with a cylindrical mounting flange (28, see Figure 2).

D7 discloses an internal protection tube (hollow metal stylet 1, see figures) which is not combined with a stiffened elongation like the invention. Moreover, it is not designed to interact with the needle body.

- 3.3 With respect to the above findings, the subject-matter of the independent claims 1 and 2 is novel.
4. Since the first instance decision was exclusively based on lack of novelty of claim 2 then on file and on lack of inventive step of claims 3 to 5, the board finds it appropriate to remit the case to the first instance for further examination.
5. The board wants to emphasize that it considered exclusively the allowability of the amendments to the claims (Article 123(2) EPC) and novelty of the claimed subject-matter (Article 54 EPC) in the present case. Other requirements of the EPC, such as clarity of the dependent claims (Article 84 EPC), inventive step

(Article 56 EPC) and formal requirements (for example those of Rule 29(1) EPC) have not been considered.

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 for further prosecution on the basis of the following version of the application:

Claims:

Nos. 1 to 10 filed with facsimile of 13 September 2004;

Description:

Pages 1 to 24 filed with letter of 25 February 2003;

Drawings:

Figures 1 to 54 published in WO-A-97/45152.

The Registrar:

The Chairman:

V. Commare

T. Kriner