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D E C I S I O N
of 7 February 2003

Case Number: T 1110/01 - 3.2.2

Application Number: 96301411.3

Publication Number: 0730881

IPC: A61M 25/06

Language of the proceedings: EN

Title of invention:
Two-component needle housing for catheter introducer assembly

Applicant:
JOHNSON & JOHNSON MEDICAL, INC.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 84, 54, 56

Keyword:
"Clarity (yes)"
"Novelty and inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1110/01 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 7 February 2003

Appellant: JOHNSON & JOHNSON MEDICAL, INC.
2500 Arbrook Boulevard,
P.O. Box 90130
Arlington,
Texas 76004-3130 (US)

Representative: Mercer, Christopher Paul
Carpmaels & Ransford
43, Bloomsbury Square
London WC1A 2RA (GB)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 23 April 2001 refusing European patent application No. 96 301 411.3 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: D. Valle
J. C. M. De Preter

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal against the decision of the Examining Division to refuse the application.

The Examining Division held that claim 1 did not meet the requirements of clarity (Article 84 EPC) and of novelty (Article 54 EPC) having regard to documents:

D4: US-A-5 273 540, or:

D3: EP-A-0 578 367.

The Examining Division considered that also the dependent claims 2 to 5 and the method claim 7 were anticipated by document D4, and that the dependent claims 6 to 8 and 13 did not add inventive features, being obvious modifications which came within the scope of the customary practice followed by the person skilled in the art.

II. The appellant requested a grant of a patent on the basis of the amended claims 1 to 5 as submitted with letter of 16 January 2003, claims 6 to 13 as submitted during the oral proceedings on 23 March 2001, and retyped and submitted again with letter of 22 August 2002, and of the description, pages 1, 3 to 6 as originally filed, page 2 as filed with letter of 22 September 2000, drawings 1/3 to 3/3 as filed with letter of 22 September 2000. He requested provisionally oral proceedings.

III. Independent claim 1 as submitted with letter of 16 January 2003 reads as follows:

"A catheter introducer assembly having: a housing (1) for gripping by a user; a cannula opening (2) in the housing; a hollow sharpened cannula, extending from said housing (1) through said cannula opening (2), for piercing the skin of a patient during introduction of said catheter; a flash chamber (5) which is separate from said housing and which is attached to said housing (1), said flash chamber (5) being in fluid communication with said hollow cannula for receiving blood that travels through said cannula during catheter introduction; an attachment opening in said housing (1); and a cannula protecting device, the attachment portion of which is received in said attachment opening; wherein: said cannula is adapted to receive the catheter thereover; and said flash chamber (5) attached to said housing (1) is obtainable by fabricating said flash chamber (5) and said housing (1) as separate pieces and attaching said separate pieces together by attachment means."

IV. The appellant submitted the following arguments:

Regarding the objection of lack of clarity, the process step of separately fabricating and later attaching the flash chamber to the housing was allowable. Guidelines, paragraph 1.2, section C-III, 4.7b explained that the form that this type of claim must take was "product x obtainable by process y". The claims now submitted were written in such required form and therefore allowable in this respect. Furthermore, a skilled person would be able to determine whether or not an article made of two separate pieces had been attached together for example by melting or welding, by carefully studying the grain structure of the two parts or by markers left in the joint.

The invention was not anticipated by document D4. There was no cannula protecting device as such in document D4. Instead, there was a cannula protecting means provided by the interrelationship between the cannula (12) and the sheath (14). The cannula protecting means in document D4 was activated upon drawing the cannula backward relative to the sheath, the sheath then provided a protective means for the cannula.

Document D3 was not detrimental for the novelty of claim 1 either. The extension tube (70), Figure 12, could not by itself form a flash chamber: only when it was used as an extension for the actual flash chamber (26) it could receive blood. It was therefore not a flash chamber, but an extension of a flash chamber. The extension tube was separate from the housing, but not attached to the housing, it was attached to the flash chamber. The flash chamber and the housing were not formed separately.

The application involved also an inventive step. The invention addressed the problem of manufacturing catheter introducer assemblies by molding (see page 2, from line 24). Such devices had a complex shape and therefore were difficult to produce. The solution provided by the invention was to manufacture the flash chamber separately and then attaching it to the housing at a later stage of the manufacturing process.

Reasons for the Decision

1. *Formal matters.*

The amendments to claim 1, to the description and to the drawings comply with Article 123(2) EPC. The Examining Division did not raise an objection in this respect either.

Claim 1 is sufficiently clear. The objection of the Examining Division based on Article 84 EPC and on the Guidelines, part C-III, point 4.7(b), concerned the feature that the flash chamber was fabricated separately from the housing and then attached thereto. The Examining division was of the opinion that such formulation did not permit an unequivocal definition of the product since one could not judge from the finished product alone whether it was manufactured separately or in one piece.

The Board does not share such opinion. It is clear from the description and the drawings, see in particular Figure 2, that the flash chamber and the housing are two distinct pieces. Even if the flash chamber were ultrasonicly welded or adhesively attached to the housing, it is believed that an appropriate microscopic analysis would reveal a discontinuity in the molecular structure at the attachment area typical of the respective attachment method used.

2. *Novelty*

2.1 Document D4 discloses a catheter introducer assembly having a housing (14) for gripping by a user; a cannula opening (20) in the housing; a hollow sharpened

cannula (12) extending from said housing through said cannula opening (Figure 3) for piercing the skin of a patient during introduction of said catheter (column 7, lines 39 to 47); a flash chamber (10) which is separate from said housing (14) and which can be slidably inserted in said housing, said flash chamber being in fluid communication with said hollow cannula for receiving blood that travels through said cannula during catheter introduction (column 7, lines 47 to 50); an opening (22) in said housing; wherein said cannula is adapted to receive the catheter thereover and said flash chamber (10) is obtainable by fabricating said flash chamber and said housing as separate pieces.

The subject-matter of claim 1 differs therefrom in that the flash chamber is attached to the housing by attachment means and in that it provides for a separate cannula protecting device, the attachment portion of which is received in an attachment opening of the housing.

According to the description of the application in suit, the flash chamber can be attached to the housing by ultrasonic welding, adhesive, or by a press fit attachment, see EP-A-730 881, column 2, from line 18. The cannula protecting device can consist of a cap for capping the tip of the sharpened cannula after emplacement of the catheter unit, whereby the attachment mechanism of the cannula protecting device can consist of a sliding member that slides out of the housing as the capping portion of the device slides along the cannula during removal of the cannula from the catheter, see EP-A-730 881, from column 3, line 55.

In contrast thereto, document D4 discloses a flash chamber which can be slidably inserted into the housing and not attached to it by attachment means. Furthermore, document D4 does not disclose a cannula protecting device separate from the housing, the attachment portion of it being received in the housing. The Board can therefore not agree with the decision under appeal which wants to see the attachment portion of the cannula protecting device in the protrusion (32) attached to the flash chamber (10) of document D4.

2.2 Document D3, discloses a catheter introducer assembly having a housing (20) for gripping by a user; a cannula (needle) opening (78) in the housing; a hollow sharpened cannula (24) extending from said housing through said cannula opening (Figure 10) for piercing the skin of a patient during introduction of said catheter (50) (column 7, lines 39 to 45); a flash chamber (26) which is attached to said housing, said flash chamber being in fluid communication with said hollow cannula for receiving blood that travels through said cannula during catheter introduction; wherein said cannula is adapted to receive the catheter thereover; and a cannula protecting device (30).

The subject-matter of claim 1 differs therefrom in that the flash chamber is separate from the housing. In contrast thereto the flash chamber (26) of document D3 is integral with the housing (20). Furthermore the claim contains the distinguishing feature that the attachment portion of the cannula protecting device is received in an attachment opening in the housing.

The Board does not share the view - contained in the decision under appeal - that the cannula protecting

device of document D3 is attached to the housing through the longitudinal slot (36). In fact, the cannula protecting device (needle guard 30) is inserted in the housing and its outer surface (96) slides along the inner surface of the housing (20), see Figure 7(c), whereas the longitudinal slot (36) merely receives the base (27) of the flash chamber after insertion of the needle guard (30) in the housing (20), compare Figures 1, 2 and 3. Furthermore, the attachment portion of the cannula protecting device is not received in an opening of the housing, but contained into the two wings of the housing. Finally, the flash chamber extension (70) of document D3 can not be intended as the flash chamber in the sense of the invention, because the flash chamber of the invention is designed to be directly attached to the housing.

2.3 The remaining documents of the available prior art are further away from the claimed invention. Accordingly, the subject-matter of claim 1 is novel.

3. *Inventive step*

3.1 Starting from document D4, the technical problem to be solved is to provide a device which is easy and inexpensive to manufacture, and which can be safely handled, especially during the removal of the sharpened cannula, in order to avoid sticking the skin of the operator, see EP-A-730 881, column 1, from line 55.

The problem is solved by providing a cannula protecting device which is separate from the housing and attached to the housing through an independent attachment opening, and by providing a flash chamber which is independently fabricated and successively attached to

the housing.

By providing distinct elements, each with a well defined function: the housing, for providing a grip to the user and for receiving the further elements; the cannula protecting device, to be received into the housing through a separate opening; and the flash chamber; independently manufactured and successively attached to the housing, the design of the pieces can be more efficient and flexible.

There are no reasons to challenge the inventive step of claim 1 on the basis of document D4, because the devices are of substantially different design.

3.2 Considering document D3 as the starting point for the test of inventive step, it should be noted that document D3 has a complicated form, difficult to be reproduced by molding, see in particular the connection of the flash chamber to the housing through the base (27). The problem to be solved has therefore to be seen in providing a reliable and safe catheter introducer assembly whose fabrication process is easy and inexpensive, see column 2, from line 8 of EP-A-730 881.

Such purpose is essentially achieved by providing a flash chamber separate from the housing and successively attached to the housing, and by providing a separate attachment opening for receiving the cannula protecting device.

There are no reasons to believe that a person skilled in the art would modify the device according to document D3 and arrive at the invention without any

inventive step being involved, because no hints are disclosed which can lead to it.

4. The further documents of the available prior art appear less relevant for the assessment of the inventive step. Accordingly, claim 1, together with the corresponding independent method claim 7 and the appended dependent claims comply with the prescriptions of the EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to grant a patent on the basis of claims 1 to 5 as submitted with letter of 16 January 2003, claims 6 to 13, as submitted with letter of 22 August 2002, description, pages 1, 3 to 6 as originally filed, page 2 as submitted with letter of 22 September 2000; drawings 1/3 to 3/3 as submitted with letter of 22 September 2000.

The Registrar: The Chairman:

V. Commare W. D. Weiß

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Case Number: T 1110/01 - 3.2.2

D E C I S I O N
of 8 July 2003 correcting errors in the decision
of the Technical Board of Appeal 3.2.2
of 7 February 2003

Appellant: JOHNSON & JOHNSON MEDICAL, INC.
2500 Arbrook Boulevard,
P.O. Box 90130
Arlington,
Texas 76004-3130 (US)

Representative: Mercer, Christopher Paul
Carpmaels & Ransford
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Members: D. Valle
J. C. M. De Preter

In application of Rule 89 EPC the decision given on 7 February 2003 is hereby corrected as follows:

Page 1, point 2, line 6, and page 10, in the "Order", point 2 fifth line, replace the year 2002 with the year 2001.

The Registrar: The Chairman:

V. Commare W. D. Weiß