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D E C I S I O N
of 27 September 1995

Case Number: T 0515/92 - 3.2.2

Application Number: 87300362.8

Publication Number: 0229729

IPC: A61M 5/00

Language of the proceedings: EN

Title of invention:
Implantable treatment reservoir

Applicant:
Strato Medical Corporation

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 56, 123(2)

Keyword:
"Inventive step - (yes) after amendment"

Decisions cited:
-

Catchword:
-

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Case Number: T 0515/92 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 27 September 1995

Appellant: Strato Medical Corporation
123 Brimball Avenue
Beverly, MA 01915 (US)

Representative: Harvey, David Gareth
Graham Watt & Co.
Riverhead
Sevenoaks
Kent TN13 2BN (GB)

Decision under appeal: **Decision of the Examining Division of the European Patent Office dated 3 January 1992 refusing European patent application No. 87 300 362.8 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: H. Seidenschwarz
Members: P. Dropmann
J.- C. De Preter

Summary of Facts and Submissions

I. A Notice of Appeal was filed against the decision of the Examining Division refusing European patent application No. 87 300 362.8.

The Examining Division held that the application did not meet the requirements of Articles 52(1) and 56 EPC having regard to document EP-A-0 119 596 (D1), considering that the adoption of a bayonet-type connector was but one of several possible connectors and therefore obvious. Furthermore, the Examining Division raised objections under Article 123(2) EPC.

II. Following a communication by the Board dated 18 July 1995 and two telephone conversations on 12 and 19 September 1995 between the Appellant's representative and the Rapporteur raising objections under Articles 123(2), 84 and 56 EPC, the Appellant submitted an amended set of Claims 1 to 9, an adapted description and a slightly amended Figure 1 together with arguments in favour of an inventive step.

III. The Appellant requested that the decision under appeal be set aside and a patent granted on the basis of the following documents: Claims 1 to 9, description pages 1 to 3, 3A and 4 to 13 and Figures sheet 1/3, all filed with the letter of 20 September 1995, and Figures sheets 2/3 and 3/3 as originally filed. (In Claim 9 "connection" should read "connector".)

IV. The single independent claim reads as follows:

"1. An implantable assembly comprising a device (1) having a body portion (2) formed of biocompatible material and including a chamber with an open face, a

cover (3) closing the chamber to form a closed reservoir (5) for holding treatment fluid, the body portion (2) having an outlet aperture (26) in fluid communication with the reservoir and a cannula (31) extending therefrom, and further comprising an elastically compressible catheter (11) having a central passage, and collar means to secure the catheter (11) to the cannula (31), characterised by a bayonet type coupling including a locking portion (20) on the device (1) adjacent to the outlet aperture (26) and a separate twist-lockable flanged catheter connector (17) for detachably coupling the catheter (11) and the device (1), the flanged connector having a generally tubular body (19) serving as the collar means, with radially extending flange segments (18A, 18B) and having a central bore (30), the body (19) being slidable over the catheter (11) and its bore (30) having a diameter calculated to elastically compress the catheter (11) between the bore (30) and the outer surface of the cannula, and the locking portion (20) having an input region (21) large enough to permit passage of the flange segments (18A, 18B) and an interior region (22) to accommodate the flange segments (18A, 18B) between a surface (32) of the device (1) and a confronting surface (24) for releasingly engaging the flange segments (18A, 18B) when an end of the catheter (11) is positioned over the cannula (31) and the tubular body (19) is slidingly positioned over the end of the catheter (11) and is then manipulated by a partial revolution for twist locking engagement with the locking portion (20), thereby securing the catheter (11) compressively engaged with the cannula (31)."

Reasons for the Decision

1. The appeal is admissible.

2. *Formal aspects*

No formal objections arise against Claims 1 to 9 under Articles 123(2) and 84 EPC and Rule 29 EPC. The description complies with Rule 27 EPC.

As to Article 123(2) EPC, Claims 1 essentially has its basis in original Claims 6 and 1 taking into account that original Claim 1 mentions a mating twist-lockable connector in its broadest terms. The features that the coupling is of a bayonet type, that the tubular body is slidable over the catheter and that the bore of the tubular body has a diameter calculated to elastically compress the catheter between the bore and the outer surface of the cannula, are disclosed at page 13, line 4, page 7, lines 8 to 11 and page 8, lines 1 to 4, respectively, of the description as originally filed. The feature concerning the partial revolution of the tubular body, which feature was objected to by the Examining Division, is supported by the statements at page 8, lines 22 to 24 and page 9, lines 23 and 24. In the light of the general disclosure in the description of a bayonet coupling and in view of the fact that the embodiment depicted in the figures is just a preferred one (see original page 3, lines 15 and 17 and page 10, line 16), it is not justified to restrict the scope of the invention to an assembly having a "quarter-turn revolution" bayonet connector.

As to dependent Claims 2 to 9, reference is made to original Claims 2 and 4 to 9 and to Figures 4A, B, C and 5 and the corresponding text of the description.

3. *Novelty*

Document EP-A-0 183 351 is the only one of those documents mentioned in the search report and during the examining proceedings which discloses an implantable assembly comprising a bayonet type coupling. This document, however, does not anticipate the characterising feature of Claim 1 that a separate twist-lockable flanged catheter connector is slidable over the catheter.

The claimed assembly is, therefore, novel within the meaning of Article 54 EPC over these documents and also over the state of the art acknowledged at page 1, lines 18 to 25 of the application.

4. *Inventive step*

4.1 Document EP-A-0 183 351 is an Article 54(3) EPC document and is hence not applicable for assessing inventive step.

4.2 The Examining Division considered document EP-A-0 119 596 (D1) as the closest prior art document. The latter disclosed an assembly wherein the catheter (1) can be connected to and disconnected from the reservoir device (2) having a stub (3) provided with ribs and a bead at its end. According to page 7, lines 24 to 27 of document D1, the end of the catheter tube (1) is shaped as a sleeve which can be pushed over the end bead and the ribs, thus forming a plug connection (4). Although Figure 1 shows that the catheter tube (1) and the sleeve are not made of a single piece, it is clear from the above statement at page 7 and the function of the sleeve that the latter is

firmly joined to the catheter tube and thus does not permit the catheter to be sized before connection of the catheter to the reservoir device, which sizing, however, is an important effect obtained by the claimed assembly.

For this reason, the Board takes the view that it is not document D1 but the art acknowledged at page 1, line 18 to page 2, line 2 of the application which represents the closest prior art for considering inventive step. The Appellant shares this opinion. This closest prior art comprises an assembly having a catheter which fits over a male tube or cannula projecting from the reservoir housing and is secured thereto by placing an external collar about the catheter. The assembly permits the reservoir housing to be sutured in position and the catheter to be installed in a vein and sized before connection of the catheter to the reservoir housing. However, as furthermore stated in the sentence bridging pages 1 and 2 of the application, the connection of the catheter requires care and it relies solely on elastic gripping to remain attached.

4.3 In the light of the above closest prior art and its disadvantages, the technical problem underlying the present invention can be seen, in accordance with the statements at page 2, lines 3 to 7 of the application, as providing an implantable assembly comprising a reservoir device which permits the direct and simple yet secure connection to a catheter after the suturing of the reservoir device in the body and the placement and sizing of the catheter.

The problem is solved by an assembly according to Claim 1, which is delineated over the above closest prior art. Briefly, the simple yet secure connection is essentially achieved by a **specific** bayonet type coupling

including a particular locking portion (20) on the device (1) and a separate twist-lockable flanged catheter connector (17) being slidable over the catheter and having the features specified in the characterising portion of Claim 1.

4.4 None of the Article 54(2) EPC documents mentioned in the search report and during the examining proceedings reveals a bayonet type coupling. These documents, therefore, cannot have given a hint that the problem could and would have been solved by the use of such a coupling. In particular, there is no indication in document D1, which document, as noted in point 4.2 above, discloses a sleeve firmly joined to the catheter tube, that the sleeve might advantageously be replaced by a separate, slidable bayonet type connector. Neither does the closest prior art stated in point 4.2 above suggest such a bayonet type coupling.

Thus, the question to be answered is whether the subject-matter of Claim 1 is obvious in the light of the common general knowledge of the skilled person who is familiar with several possible connectors including bayonet type connectors used in other fields. The Examining Division held that the choice of the bayonet type connector out of these possible connectors was obvious in view of the problem to be solved and it cited the bayonet mount of a camera lens as a self-evident example.

The Board cannot accept the argument that the skilled person faced with the above problem of simple yet secure connection of a catheter to a reservoir housing would look to such a remote field as camera technology which field has nothing to do with fluid connection. However, the Board accepts that it appears obvious for the skilled person to take conventional bayonet type

connections into consideration. The replacement of the collar means of the prior art assembly by such a conventional bayonet connection would not, however, lead to the assembly specified in Claim 1. Indeed, Claim 1 mentions a very particular locking portion and a very specific bayonet type connector which, despite being separate and slidable on the catheter, affords a secure and leak-tight union between the catheter and the cannula since the connector is dimensioned as to effect the elastic compressing of the catheter onto the cannula.

In the absence of any corresponding relevant state of the art, the specific bayonet type connection and thus the assembly according to Claim 1 is considered as involving an inventive step in accordance with Article 56 EPC.

5. Hence, the subject-matter of Claim 1 is patentable having regard to Articles 52(1), 54 and 56 EPC.

Dependent Claims 2 to 9 define particular embodiments and meet likewise the requirements 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 first instance with the order to grant a patent in the following version:

Description: Pages 1 to 3, 3A and 4 to 13 filed with the letter of 20 September 1995.

Claims: Nos. 1 to 9 filed with the letter of 20 September 1995. In Claim 9 "connection" should read "connector".

Drawings: Sheets 2/3 and 3/3 as originally filed, sheet 1/3 filed with the letter of 20 September 1995.

The Registrar:

S. Fabiani

The Chairman:

S. Seidenschwarz