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File No.: T 0701/91 - 3.2.2  
Application No.: 84 301 056.2  
Publication No.: 0 117 695  
Classification: A61M 1/00  
Title of invention: External ventricular drainage assembly

**D E C I S I O N**  
of 4 October 1993

Applicant: Baxter International Inc.  
Proprietor of the patent: -  
Opponent: -

Headword: -

EPC: Art. 56

Keyword: "Inventive step (yes); exclusion of hindsight"

**Headnote**  
**Catchwords**



Case Number: T 0701/91 - 3.2.2

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.2  
of 4 October 1993

**Appellant:** Baxter International Inc.  
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Illinois 60015 (US)

**Representative:** Seaborn, George Stephen  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office dated 15 March 1991  
refusing European patent application  
No. 84 301 056.2 pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** P. Dropmann  
**Members:** M. Noël  
F. Benussi

**Summary of Facts and Submissions**

- I. European patent application No. 84 301 056.2 (publication No. 0 117 695) was refused by a decision of the Examining Division on the ground that the subject-matter of the claims did not involve an inventive step having regard to the prior art documents
- (1) US-A-3 957 050 and  
(2) US-A-3 604 420.
- II. The reason for the refusal was that the subject-matter of Claim 1 differed from that of the closest prior art document (1) by three groups of features representing independent solutions of three partial problems, without any relationship to each other, so that the subject-matter of Claim 1 could not be regarded as a real combination of features. Since each solution considered separately was either based on common general knowledge of a person skilled in the art or derivable from the prior art documents, the subject-matter of Claim 1 was regarded as obvious by the first instance.
- III. A Notice of Appeal against this decision was filed by the Appellant on 19 April 1991 and the appeal fee was paid in due time. In support of the Statement of Grounds received on 23 July 1991, new claims were submitted.
- IV. In a communication of 11 March 1993 the Board informed the Appellant of its provisional opinion agreeing that a new Claim 1 reworded in a one-part form and amended in the sense indicated therein would be acceptable as regards inventive step with respect to the state of the art.

V. Taking account of the suggestions made by the Board, the Appellant submitted in his reply of 21 June 1993 a new set of claims along with corresponding amendments in the introductory part of the description so as to specify the technical problem to be solved with respect to the embodiment known from the closest prior art.

Claim 1 in suit reads as follows:

"An external ventricular drainage assembly (10) comprising:

- (a) a ventricular drainage catheter (14) for placement in the ventricles of a patient's brain for receiving cerebrospinal fluid;
- (b) retention means (18) connected to the catheter for securing the catheter to the patient and for preventing relative movement between the catheter and patient;
- (c) valve means (22) connected to the catheter for selectively opening and closing a fluid flow path of the external ventricular drainage assembly to fluid flow;

the fluid flow path extending through the catheter and, in the order given, through the valve means (22) and

- (d) an adapter means (30) connected to the valve means for providing access to the fluid flow path of the assembly;
- (e) a one-way valve (34) connected to the adapter means;
- (f) a first length of flexible tubing (36) and a second length (42) of flexible tubing, the first length of flexible tubing being connected to the one-way valve and being provided with a clamp (38) for selectively opening and closing the first length of flexible tubing to fluid flow therethrough along the fluid flow path; and

- (g) coupling means (40) having a first member connected to the first length of flexible tubing and a second member connected to the second length of flexible tubing, the second length of flexible tubing being provided with a clamp (44) for selectively opening and closing the second length of tubing to fluid flow therethrough along the fluid flow path, the first and second members selectively interconnecting and disconnecting the first and second lengths of flexible tubing;  
the fluid flow path extending to
- (h) a collection reservoir (46) for collecting cerebrospinal fluid, the reservoir having an entry port (50) which is connected to the second length of flexible tubing through a drip chamber (48) and having an outlet port (52) from which collected cerebrospinal fluid can be removed."

VI. The Appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the following documents:

- Claims 1 to 16 and recasted full text of the description (pages 1 to 8) received on 27 September 1993,
- Drawing as originally filed.

## Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

Claim 1 has been appropriately re-worded in the one-part form, in view of a number of structural differences and of a different arrangement of the known features with respect to the embodiment disclosed in the closest prior art document.

The subject-matter of Claim 1 is based on Claim 1 in the version as originally filed, implemented by features drawn up from original Claims 16 and 17, amplified in terms of their disclosed functions.

Since all features were already the subject of the original application considered as a whole, the requirements of Article 123(2) EPC are satisfied.

3. *Closest prior art*

The Board considers document (1) as the state of the art closest to the invention, in agreement with both the first instance and the Appellant.

In this respect, document (1) discloses an external ventricular drainage assembly comprising a ventricular drainage cannula for placing in the ventricles of the brain of a patient for receiving cerebrospinal fluid, a fluid flow path extending through the cannula and through flexible tubing 15 connected to the cannula, the tubing being provided with two clamps 71,75 for selectively opening and closing the external ventricular

drainage assembly to fluid flow and a rubber squeeze bulb 73 between the clamps, which provides access to the fluid flow path of the assembly, a one-way valve 57,69 being connected to the flexible tubing, a collection reservoir 17 for collecting cerebrospinal fluid being connected through a manometer 19 to the one-way valve, and the fluid flow path extending from the flexible tubing through the one-way valve and the manometer to the collection reservoir.

The concept of this known device refers to the ability of controlling the pressure of the cerebrospinal fluid passing from the ventricles of a patient's brain to a collection bag and to allow the patency of the drainage assembly to be quickly ascertained. By varying the relative height positions of the concentric tubes 31,33 of the manometric means, the pressure of the cerebrospinal fluid can be varied. Observation of the meniscus formation between the tubes further allows the fluid pulsations to be noted and thus the patency of the drainage can be easily ascertained.

4. *Novelty*

In addition to the ventricular drainage assembly described in document (1) having no retention means and no valve means in the sense of the claimed subject-matter, the known device still differs from that of Claim 1 by the catheter being connected to the reservoir via the manometer by means of a single one-part flexible tubing. For that reason the reservoir is not designed to be exchanged. Therefore the tubing is not provided with coupling means and a second clamp is also not necessary. Further, the reservoir is not connected to the flexible tubing through a drip chamber.

The drainage system described in document (2) does not come closer to the subject-matter of the present application. This document discloses essentially that a collection reservoir can be provided with a drip chamber for controlling the fluid flow drained by the tubing. However, most of the remaining features of Claim 1 are missing from this known embodiment, in particular coupling means for selectively connecting and disconnecting the reservoir from the catheter.

Since none of the cited documents mentions in combination all the features of Claim 1, its subject-matter must be regarded as novel over the prior art, according to Article 54(1) EPC.

5. *Problem and solution*

In the Statement of Grounds of Appeal the Appellant admitted, which is also accepted by the Board, that the various features contained in Claim 1 aimed to resolve a number of partial problems, such as:

- exchanging the reservoir in which the fluid is collected,
- monitoring the rate of fluid flow,
- maintaining the pressure in the patient's brain at a desired level, and
- preventing the introduction of bacteria or other infectious agents to the patient's brain.

In fact, it is emphasised by both the patent application and the Appellant's statements made during the previous and present procedures that a major aspect of the present application refers to replacing the collection reservoir in good condition of sterility once it has become full, i.e. while keeping the drainage assembly closed to the introduction of bacteria.



For the Board, this represents the objective technical problem to be solved with respect to the teaching of the closest prior art which also discloses a closed drainage system, however without any possibility to replace the collection reservoir safely.

This problem is solved by the features recited in Claim 1, in particular by the catheter being connected to the reservoir by means of a flexible tubing made of two parts of appropriate length interconnected by a coupling means and by a pair of clamps being located on each side of said coupling means, on the respective parts of the tubing. The first clamp, i.e. the clamp located on the first tubing portion, seen in the direction of fluid flow, is most important since whilst the coupling means is in its disconnected state so that the collection reservoir can be safely removed, closing of said first clamp prevents infectious agents from entering the first length of the flexible tubing and, at the same time, enables the fluid pressure to be maintained in the patient's brain.

6. *Inventive step*

6.1 In the device described in document (1) the end of the flexible tubing 15 is attached to a valve means 57, which in turn is mounted in the base member of the manometer. Clearly, the known fastening is not designed to be disconnected at will and thus such arrangement is not similar to a quick release coupling means placed on the tubing such as disclosed in the application.

Starting from the ventricular drainage assembly disclosed in document (1), the person skilled in the art who is confronted with the problem set out above would not be led from this document to means for replacing the collection reservoir safely and rapidly. Should the

skilled person have decided nevertheless to disconnect the only connecting portions 21,23 located on the flexible tubing close to the patient's head, with the view to exchanging the reservoir and the tubing as a whole, the patient's brain would not be protected any more against the introduction of infectious agents nor against a pressure drop, which may be both highly detrimental to the patient. Also the closure of the nearest clamp 75 would be totally useless, due to its location on the downstream side of the connecting portions, as the clamp would be removed together with the tubing.

6.2 The skilled person certainly knows, on the basis of his general technical knowledge, that a fluid flow can be interrupted as the need arises by means of a rapid action hose coupling placed in the fluidic circuit. However, since the basic problem of replacing the collection reservoir was addressed in none of the cited documents, nor was there any particular instruction or hint leading the skilled person to the solution, the statement after the event that the means used for joining together two portions of the tubing was obvious only because of the simplicity of the solution, would, in the Board's opinion, be an *ex post facto* analysis.

6.3 Yet, had the skilled person decided to introduce a coupling means and a second clamp on the tubing portion 15 shown in Fig. 1 of document (1), the first clamp being identified by the clamp 71, he would still not have arrived at the claimed subject-matter since the coupling and clamp elements would be located as in document (1) on the upstream side of the one-way valve 57, while in the embodiment according to the application the coupling means and clamps are set on the downstream side of both the one-way valve 34 and the valve means 22. Thus, in addition to the deficiencies already

mentioned in section 4 above, further modifications would have still been necessary to re-establish the succession of elements in the order they are claimed. In the Board's view, such considerations already support the assumption of an inventive step.

6.4 Examination by the Board of the remaining distinctive features of Claim 1 with respect to the embodiment of document (1) can be dispensed with, since in the present case an inventive step has been recognised and it matters little whether the rest of the features are forming a real combination in the sense of their functional relationship. According to T 389/86, 31 March 1987, points 4.3 and 4.11, unpublished, for a claim based on an assumed combination of features to be inventive, the main issue to be considered is whether or not at least one feature or group of features, which represents the solution of at least one partial problem referred to in the application, is new and inventive having regard to the state of the art.

6.5 In the present case, since as stated above at least one essential feature was not obvious to the person skilled in the art, the subject-matter of Claim 1 must be regarded as inventive over the prior art within the meaning of Article 56 EPC. Consequently, dependent Claims 2 to 16 are also allowable.

**Order**

**For these reasons, it is decided that:**

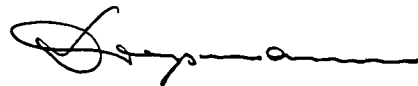
1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to grant a patent on the basis of the documents listed in section VI above.

The Registrar:



S. Fabiani

The Chairman:



P. Dropmann

*P. Wolf*  
*2.11.93*