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**D E C I S I O N**  
**of 14 October 1994**

**Case Number:** T 0044/91 - 3.2.5

**Application Number:** 83902012.0

**Publication Number:** 0112356

**IPC:** B86B 3/04

**Language of the proceedings:** EN

**Title of invention:**  
Fluid communication device

**Patentee:**  
BAXTER TRAVENOL LABORATORIES, INC.

**Opponent:**  
Fresenius AG

**Headword:**  
-

**Relevant legal provisions:**  
EPC Art. 56

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

**Decisions cited:**  
-

**Catchword:**  
-



Case Number: T 0044/91 - 3.2.5

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.5  
of 14 October 1994

**Appellant:** BAXTER TRAVENOL LABORATORIES, INC.  
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Deerfield, IL 60015 (US)

**Representative:** MacGregor, Gordon  
ERIC POTTER & CLARKSON  
St. Mary's Court  
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Nottingham, NG1 1LE (GB)

**Respondent:** Fresenius AG  
(Opponent) D-61343 Bad Homburg v.d. Höhe (DE)

**Representative:** Dr Fuchs, Dr Luderschmidt  
Dr Mehler, Dipl.-Ing. Weiss  
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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office orally given on  
25 September 1990 and posted on 5 November 1990  
by which the European patent No. 0 112 356 had  
been revoked pursuant to Article 102(1) EPC.

**Composition of the Board:**

**Chairman:** C. V. Payraudeau  
**Members:** C. G. F. Biggio  
H. P. Ostertag

## Summary of Facts and Submissions

I. The Appellant (Proprietor of the patent) lodged an appeal against the decision of the Opposition Division, by which the European patent No. 0 112 356 had been revoked on the ground that its subject-matter did not involve an inventive step within the meaning of Article 56 EPC having regard to the teachings disclosed by the documents DE-U-7 736 090 (E4) and DE-A-2 920 975 (E1).

II. Oral proceedings were held before the Board of Appeal.

(i) The Appellant requested that the decision under appeal be set aside and as main request that the patent be maintained in amended form on the basis of Claims 1 to 11 and column 1 and 2 of the description filed at the oral proceedings together with column 3 to column 6, line 43 of the description and the drawings of the patent as granted, and as an auxiliary request that the patent be maintained on the basis of Claims 1 to 7 filed at the oral proceedings together with the drawings of the patent as granted and a description to be amended accordingly.

The Respondent (Opponent) requested that the appeal be dismissed.

(ii) Claim 1 according to the main request reads:

"1. A fluid communication device comprising a plurality of fluid lines in fluid communication, via respective peristaltic pumps, with a common fluid passageway, the device comprising

a plurality of first fluid lines (40, 40', 40''), each said first fluid line connecting a respective fluid connector (36, 36', 36'') to a respective first pump fitting (32, 32', 32'') providing a fluid path therebetween; the device being characterised by

a plurality of pump tubing segments (30, 30', 30'') maintained in tension connecting each of said first pump fittings to a respective second pump fitting (34, 34', 34'') furnishing a fluid path therebetween;

a plurality of second fluid lines (42, 42', 42''), each second fluid line connecting a respective second pump fitting to a common junction block (20);

including a fluid passageway (66) in fluid communication with each of the second fluid lines (42, 42', 42'') and an exit port (74) communicating with said fluid passageway (66) to provide a path to a receiving container (18)".

Claim 1 according to the auxiliary request reads:

"1. A fluid communication device comprising a plurality of fluid lines (40, 40', 40''; 30, 30', 30''; 42, 42', 42'') from respective solution containers and connected in fluid communication, via respective peristaltic pumps (28), with a common junction block (20) providing fluid communication between the fluid lines and an exit port (74), leading to a receiving container, the device being characterised in that: -

it provides a sterile and unitized fluid path and comprises:-

a plurality of first fluid lines (40, 40', 40''), each said first fluid line connecting a respective solution container connector (36, 36',

36'') to a respective first pump fitting (32, 32', 32'') providing a fluid path therebetween;

a plurality of pump tubing segments (30, 30', 30'') connecting each of said first pump fittings to a respective second pump fitting (34, 34', 34'') furnishing a fluid path therebetween;

a plurality of second fluid lines (42, 42', 42''), each second fluid line connecting a respective second pump fitting to said common junction block (20);

the first and second pump fittings being placed in respective inlets and exits of the pump housings with the segments (30, 30', 30'') engaged about pump rollers (28) to maintain the segments in tension;

the block including a fluid passageway (66) in fluid communication with each of the second fluid lines (42, 42', 42'') and the exit port (74) communicating with said fluid passageway (66) to provide a path for further fluid communication externally of the junction block;

a cover (78) being provided to cover said exit port (74) to prevent particulate matter from accumulating thereon;

the cover including a retaining ring (82) securing the cover to the junction block (20), and a closure member (80) connected to the retaining ring by a flexible arm (84), the flexible arm maintaining the retaining ring (82) and closure member (80) in substantially the same plane in the uncovering position, the closure member (80) having an internal side (92) facing downwardly when the exit port (74) faces upwardly, the flexible arm (84) being twistable to allow the interior side (92) to cover the exit port (74) in the covering position".

(iii) The Appellant argued essentially as follows:

The present invention relates to a fluid communication device for mixing and transferring solutions, in particular for compounding of hyperalimentation solutions under laboratory conditions. To ensure sterility, such compounding is conventionally performed under a laminar flow hood using purified air, a procedure which is cumbersome, error-prone and has other disadvantages, such as filter clogging. The device according to the present invention seeks to overcome these disadvantages.

The prior art on which the Opposition Division relied in its decision, i.e. documents E4 and E1, is not concerned with the compounding of solutions under laboratory conditions: document E4 relates to parenteral infusion through a catheter to a patient, whereas document E1 relates to a portable infusion device, whereby the mixed fluid is also directly administered to a patient. The person skilled in the art would therefore not take into account the documents E4 and E1, which are concerned with administering fluids to patients, when addressing the problem of compounding of solutions under laboratory conditions. In order to bring out clearly this essential difference between the invention and the prior art, Claim 1 according to the main request now contains a reference to a receiving container.

With respect to the auxiliary request the Appellant argued that there is no disclosure in any of the prior art of a junction block having an exit port closable by a cover with all the features of Claim 1.

- (iv) The Respondent argued essentially as follows:  
The distinction made by the Appellant between mixing and transferring solutions in the laboratory of a hospital and mixing solutions in the ward of a hospital and transferring the compounded solution directly to a patient is not only artificial, it is also not expressed in the claims as granted. A reference to a receiving container in Claim 1 cannot impart an inventive step to that claim. The combined teachings of documents E4 and E1 lead the person skilled in the art directly to the claimed subject-matter.

The additional feature of Claim 1 according to the auxiliary request, i.e. that the junction block is provided with a cover with its internal face facing downward when not used, cannot support an inventive step, especially since means which would keep the junction block in an upright position are not defined in Claim 1.

## **Reasons for the Decision**

### **1. Amendments**

- 1.1 Claim 1 according to the main request differs from Claim 1 as granted in that the phrase "an exit port (74) communicating with said fluid passageway (66) to provide a path for further fluid communication externally of the junction block" is replaced by the phrase "an exit port (74) communicating with said fluid passageway (66) to provide a path to a receiving container (18)". The latter feature is derived from column 3, line 65 to column 4, line 22, see also Figure 1. There is no contravention of Article 123(3) EPC, since the added

phrase "to a receiving container" does not provide any technical contribution to the subject-matter of the claimed invention (the receiving container is shown in phantom in Figure 1).

The amendment to the description entails the insertion - after line 50 of column 2 - of the sentence "The features of the present invention are as set out in Claim 1".

The amended documents are, therefore, not objectionable under Article 123 EPC.

1.2 The revised Claim 1 according to the auxiliary request is substantially based on Claims 1 to 5 as granted. Apart from some minor editorial changes, such as the inclusion of additional reference signs, the following amendments have been made:

1. the expression "from respective solution containers" has been inserted in the preamble (cf. Figure 1);
2. the expression "leading to a receiving container" has been inserted in the preamble (see Point 1.1);
3. the sentence "it provides a sterile and unitized fluid path" has been added (based on column 2, lines 39 to 41);
4. the phrase "pump tubing segments (30, 30', 30'') maintained in tension" is replaced by the phrase "the first and second pump fittings being placed in respective inlets and exits of the pump housings with the segments (30, 30', 30'') engaged about pump rollers (28) to maintain the segments

in tension"; this passage is based on column 4, lines 28 to 34;

5. the added passage "a cover (78) being provided to cover said exit port (74) .. in the covering position" is based on column 3, lines 20 to 33, column 6, lines 8 to 13, and on Claims 2 to 5 as granted. The phrase "the closure member (80) having an internal side (92) facing downwardly when the exit port (74) faces upwardly" clarifies the terms upwardly and downwardly, cf. Figures 2 and 3. For clarity's sake, the following changes in terminology have been made: "cover (78)" instead of "closure member (78)" (cf. column 5, line 62; the reference number 80 denotes the closure member); "flexible arm (84)" instead of "flexible member (64)" (cf. column 5, line 65); "twistable" instead of "rotatable" (cf. column 6, line 24).

The first four amendments can be viewed as clarifications; the amendments under point 5. are primarily a limitation of the scope of protection conferred. It follows from the above that the amended claim does not contravene Article 123 EPC.

2. *Novelty (main and auxiliary request)*

None of the available documents discloses a fluid communication device comprising all the features as specified in Claim 1 according to the main and the auxiliary request, respectively. Since novelty has not been in dispute, there is no need for further detailed substantiation of this matter.

The subject-matter of Claim 1 of both the main and the auxiliary request is therefore new in the sense of Article 54 (1) and (2) EPC.

3. *Inventive step (main request)*

3.1 The present invention relates to a fluid communication device for mixing and transferring solutions.

Document E4, which in the view of the Board represents the closest state of the art, discloses (see page 4, lines 11 to 29 and Figure 1) a device for mixing and transferring solutions, which device comprises a plurality of fluid lines from respective solution containers and a common junction block providing fluid communication between the fluid lines and an exit port which leads to a patient. The force driving the fluid through the fluid lines is gravity.

3.2 The subject-matter of Claim 1 according to the main request differs from what is disclosed in document E4 in that:

(a) peristaltic pumps having a plurality of pump tubing segments having first and second pump fittings, which segments are maintained in tension, are inserted in the fluid lines between the junction block and the respective solution containers;

(b) the exit port provides a path to a receiving container (18).

3.3 No positive contribution to inventive step can be seen in introducing feature (a) into the device according to document E4, since such peristaltic pumps are described in document E1 as providing the same advantages as in

the device according to the patent in suit. Since in peristaltic pumps the fluid to be transferred does not come into contact with any part of the pump, these pumps are obviously preferred for sterile applications. The person skilled in the art would therefore regard it as a normal design option to include feature (a) in the device according to document E4 in order to solve the stated problem (e.g. to control the flow rate).

- 3.4 With regard to distinguishing feature (b), it is noted that a mixing chamber or junction block of a fluid communication device for mixing and transferring solutions must necessarily have an exit port to provide a path for further fluid communication externally of that junction block in order to transfer the fluid. In the view of the Board it is quite immaterial for the functioning of the device whether the exit port leads to a receiving container or to a patient. To put it differently, the reference "to a receiving container" does not provide any technical contribution to the subject-matter of the claimed invention (cf. Point 1.1).

It follows that feature (b) cannot by itself impart an inventive step to the claimed subject-matter.

- 3.5 The Appellant has contended that the person skilled in the art would not consider fluid communication devices for mixing solutions and administering solutions directly to patients when addressing the problem of mixing and transferring solutions to a receiving container.

The Board cannot agree with this contention for the following reasons. The background of the invention is briefly explained in column 1, lines 4 to 8 of the description, where it is said that the present invention pertains to a fluid communication device for mixing and

transferring solutions, and, more particularly, to a device especially useful in high speed compounding of hyperalimentation solutions. The patent specification continues: "Hyperalimentation therapy is the intravenous feeding of, for example, a protein-carbohydrate mixture to a patient" (emphasis added). It follows that the use of the device of present invention is not necessarily restricted to a laboratory environment, cf. also the wording of Claim 1 as granted. Introducing a reference to a receiving container in Claim 1 does not radically change the field of application of the fluid communication device (see also Point 3.4). The person skilled in the art seeking to improve known fluid communication devices is therefore not dissuaded from applying the teachings of documents E4 and E1 in order to solve the problem posed.

3.6 Consequently, the subject-matter of Claim 1 according to the main request does not involve an inventive step within the meaning of Article 56 EPC.

4. *Inventive step (auxiliary request)*

4.1 None of the cited documents discloses the feature that has been added to Claim 1, viz. "a cover being provided to cover the exit port to prevent particulate matter from accumulating thereon, said cover including a retaining ring securing the cover to the junction block, and a closure member connected to the retaining ring by a flexible arm, the flexible arm maintaining the retaining ring and closure member in substantially the same plane in the uncovering position, the closure member having an internal side facing downwardly when the exit port faces upwardly, the flexible arm being twistable to allow the interior side to cover the exit port in the covering position".

The document US-A-2 814 404, which is mentioned in the European Search Report, discloses (see e.g. column 1, lines 54 to 60, column 2, line 55 to column 5, line 14 and the Figures) a bottle cap (10) having an internal side for sealing the entrance of bottle, so designed that the cap (10) may be seated or removed with only one hand in operation, said cap (10) being provided with a flexible securing tab (34) formed integrally therewith, said securing tab (34) terminating in a loop portion (36), which is adapted to be placed over the neck of a bottle, thereby preventing the cap from getting lost when the cap is not seated.

The Board notes, however, that (see e.g. the embodiment of Figure 7 of said US patent) the internal side of the cap is oriented upwards when the cap is removed and the securing tab is substantially in the same plane as the loop portion (36), and that twisting of the flexible securing tab is not foreseen for seating the cap.

4.2 The cover according to the patent in suit protects the exit port from contamination when the exit port is not in use. The cover is flexibly connected to the junction block so that it cannot inadvertently become dislodged. When the fluid communication device is in use, the closing member is oriented with its internal side facing downward. By this construction particulate matter is prevented from accumulating on the internal side of the closure member when the device is in use. After the mixing operation the closure member is twisted about the axis of the flexible arm to cover the exit port, so that its internal side, which is substantially free of particulate matter, cannot contaminate the internal fluid passageway of the junction block.

The cover is thus seen to contribute to the object of the invention, i.e. to provide a device for mixing and

transferring solutions with a unitized, sterile, quick and economical fluid path.

4.3 The Respondent has contended that the various hoses connected to the junction block are lying in disarray on a tabletop or the like and that these hoses are likely to topple the junction block, especially since means to keep the junction block in an upright position are not defined in the claim. The Respondent concluded that when the junction block is not in an upright position, particulate matter may accumulate on the internal side of the closure member, so that the fluid passageway internal to the junction block may become contaminated upon closing the exit port.

4.4 The Board cannot agree with this reasoning. A necessary condition for any technical apparatus to work properly is that the apparatus is operated and handled in an appropriate manner. The fluid communication device according to the invention is no exception to this principle. The new Claim 1 according to the auxiliary request clearly prescribes that the exit port must face upwards (cf. also Figures 1 to 3). This is a clear teaching for the person skilled in the art how to set up the fluid communication device.

4.5 Since none of the cited documents discloses a cover with all the features of Claim 1, the person skilled in the art receives no hint or indication from these documents which could lead to the claimed subject-matter. The person skilled in the art, starting from the fluid communication device for mixing and transferring solutions according to document E4 or E1, will therefore not arrive at the subject-matter according to Claim 1, either by his expert knowledge alone, or in combination with any other teaching of the cited prior art.

5. In view of the above, the patent as granted can be maintained with the new independent Claim 1 according to the auxiliary request together with the dependent Claims 2 to 7 concerning particular embodiments of the subject-matter of Claim 1.

However, the description must be brought into conformity with the new claims.

To meet the requirements of Rule 27(1)(b) EPC, the documents E4, E1 and US-A-2 814 404 must be identified in the description and the relevant background art disclosed therein should be briefly discussed.

The units "inches" expressed in column 4, line 26, do not meet the requirements of Rule 35(12) EPC and should be replaced by the appropriate SI unit "m". The present expressions should, however, be retained in parentheses after the replacement expressions.

## Order


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

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent on the basis of the auxiliary request of the Appellant, with a description to be correspondingly amended (see Point 5 of Reasons for the decision).

The Registrar:

  
A. Townsend

The Chairman:

  
C. Payraudeau