

Publication in the Official Journal ~~Yes~~ / No

File Number: T 558/89 - 3.2.2

Application No.: 84 106 973.5

Publication No.: 0 134 436

Title of invention: System for extracorporeal blood treatment

Classification: A61M 1/14

D E C I S I O N  
of 5 November 1991

Proprietor of the patent: Gambro Lundia AB

Opponent: Fresenius AG

Headword:

EPC Article 56

Keyword: "Inventive step (yes)"

Headnote



Case Number : T 558/89 - 3.2.2

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.2  
of 5 November 1991

**Appellant :**  
(Opponent) Fresenius AG  
Gluckensteinweg 5  
W - 6380 Bad Homburg (DE)

**Representative :**  
Görtz, Dr. Fuchs, Dr. Luderschmidt  
Patentanwälte  
Sonnenberger Straße 100  
Postfach 26 26  
W - 6200 Wiesbaden (DE)

**Respondent :**  
(Proprietor of the patent) Gambro Lundia AB  
Box 10101  
S - 22010 Lund (SE)

**Representative :**  
Boberg, Nils Gunnar Erik  
Gambro AB  
Patent Department  
Box 10101  
S - 22010 Lund (SE)

**Decision under appeal :** Decision of Opposition Division of the European Patent Office dated 19 July 1989, notified on 3 August 1989, rejecting the opposition filed against European patent No. 0 134 436 pursuant to Article 102(2) EPC.

**Composition of the Board :**

**Chairman :** G. Szabo  
**Members :** P. Dropmann  
F. Benussi

### Summary of Facts and Submissions

I. European patent No. 0 134 436 comprising nine claims was granted on 7 January 1988 on the basis of European patent application No. 84 106 973.5 filed on 18 June 1984.

II. Claim 1, the only independent claim, is worded as follows:

"A system for extracorporeal blood treatment comprising a monitor (3) for the control of the course of the treatment, a treatment unit (27) for the treatment itself and a tube system for the conducting of blood from a patient to the treatment unit (27) and back to the patient under control by the monitor (3), wherein said tube system is in the form of a substantially rigid cassette (1) which is adapted so as to be fixed on, and connected to, the monitor (3) in such a manner that the desired functions such as the control of pressure and/or temperature and/or pumping of the blood are transmitted directly between the monitor and the cassette through coupling of the latter to the monitor and via two flexible tubes (11, 11') to the patient and via two further connecting ducts (26, 28) to the treatment unit (27) itself, characterized by a cassettelike holder (1b) for a conventional tube system (11b, 15b, 10b, 26b, 28b, 31b) by means of which the control function of the monitor (3) is arranged to be transmitted to the conventional tube system when it is fixed to the monitor (3) by means of the holder (1b) at the place intended for fixing the cassette (1)."

III. An opposition was filed against this patent on the grounds of lack of novelty and inventive step (Article 100(a) EPC) and insufficiency of disclosure (Article 100(b) EPC).

The following state of the art documents were considered in the opposition proceedings:

- (D1) CH-A-623 134,
- (D2) CH-A-594 418 and
- (D3) GB-A-1 601 855.

- IV. By its decision taken at the oral proceedings on 19 July 1989 and notified on 3 August 1989, the Opposition Division rejected the opposition. According to the decision, the subject-matter of Claim 1 was novel and involved an inventive step and the patent disclosed the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
- V. The Appellant filed a Notice of Appeal against this decision on 22 August 1989, paying the appeal fee on the same date. In the Statement of Grounds received on 4 October 1989, the Appellant introduced document DE-A-2 845 365 (D4) into the proceedings and referred to document GB-A-2 110 564 (D5) which had been used to formulate the prior art portion of Claim 1.
- VI. The arguments presented by the Appellant in his written submissions and at the oral proceedings held on 5 November 1991 can be summarised as follows:

Document D4 did not expressly mention a cassette, but the machine or monitor 10 disclosed in this document was clearly suited to receive tube systems in the form of cassettes. Thus, this document could be construed as destroying novelty of the subject-matter of Claim 1.

Furthermore, the Appellant pointed out that document D4 defined a holder 18 suitable to be combined with any kind

of flexible tubes 54, 74, 102. The tubes were no integral parts of the holder and could thus be considered as corresponding to the conventional tube system mentioned in the patent in suit. The holder in combination with the tubes was not a cassette in the sense of the cassette specified in the preamble of Claim 1. It rather corresponded to the cassettelike holder for conventional tube systems as mentioned in the characterising portion of Claim 1 and could be used with a plurality of tube systems. Such a cassettelike holder could be considered as an adapter to be placed between the monitor and the tube system and transferring the control functions of the monitor to the conventional tube system.

The Appellant took the view that, in the light of this prior art, the subject-matter of Claim 1 had been the result of an obvious combination of a system described in document D5 forming the preamble of Claim 1 with the teaching of document D4. It, therefore, did not involve an inventive step.

- VII. In contesting these arguments, the Respondent submitted that the prior art according to document D4 did not come closer to the patent in suit than the state of the art disclosed in document D5. In particular, arrangement 11 shown in document D4, i.e. holder 18 carrying flexible tubes 54, 74, 102 and pressure control devices, was to be considered as a cassette adapted to co-operate with the special monitor 10. This cassette was of the kind disclosed in document D5 (cf. Figure 3) and mentioned in the present patent, i.e. a substantially rigid cassette comprising either integral conduits or flexible tubes assembled during manufacturing in the factory in a particular manner. These tubes could not be replaced by different types of tube systems at the place of use, e.g. in hospital. The holder 18 could not, therefore, be defined as a

cassettelike holder for conventional tube systems in the sense of the patent in suit.

There was no indication in the prior art to provide a cassettelike holder for a conventional tube system in conjunction with the systems known from documents D4 and D5, thus enabling a monitor specially designed for use with a cassette to be used with conventional tube systems.

VIII. The Appellant requests that the decision under appeal be set aside and the patent be revoked.

The Respondent requests that the appeal be dismissed and the patent be maintained as granted.

#### Reasons for the Decision

1. The appeal is admissible.
2. In view of the prima facie relevance of the late-filed document D4, the document is to be taken into consideration in accordance with Article 114(1) EPC with the approval of the Respondent.
3. Interpretation of Claim 1
  - 3.1 By making reference to document D5 in the patent in suit, the Respondent made clear which types of cassettes should be understood by the term "said tube system is in the form of a substantially rigid cassette" specified in Claim 1. This term comprises not only cassettes manufactured by blow forming or injection moulding as described in the specification and shown in Figures 12 to 14 of the patent, i.e. cassettes comprising integral conduits, but also

cassettes of the type depicted in Figure 3 of document D5 and comprising flexible tubes.

- 3.2 The term "cassettelike holder for a conventional tube system" mentioned in Claim 1 is to be interpreted in the sense that an adapter is meant which on its one side intended to be coupled to the monitor resembles the corresponding side of the cassette, whilst on its other side it is suitable to receive different kinds of conventional tube systems (cf. column 1, line 54 to column 2, line 2 of the patent specification), which can easily and simply be inserted into the holder by the user at the place of using the blood treatment system, such that the control functions of the monitor can be transmitted to the conventional tube system when being fixed to the holder.

#### 4. Novelty

The subject-matter of Claim 1 as granted is novel over the prior art documents D1 to D5. None of the documents discloses a system for extracorporeal blood treatment comprising a triple combination of a monitor, a cassette and a cassettelike holder for a conventional tube system. In particular, this applies to document D4 irrespective of whether, as suggested by the Appellant, holder 18 shown in document D4 is to be considered as corresponding to the cassettelike holder of the patent in suit or, as suggested by the Respondent, arrangement 11 of document D4 represents a cassette in the sense of the patent.

#### 5. Inventive step

- 5.1 As acknowledged by the parties, document D5 represents the state of the art which is closest to the subject-matter of Claim 1. According to this document, a system for

extracorporeal blood treatment is known which comprises all the features specified in the preamble of Claim 1.

- 5.2 The monitor and cassette, including its own tube set, of the above-mentioned prior art system are particularly adapted to one another. Thus, the monitor cannot be used with conventional or special tube systems. The use of such different kinds of tube systems together with the same monitor specially designed for use with a cassette is, however, often desirable and wanted by the doctors.
- 5.3 The objective technical problem underlying the patent in suit can thus be seen as being to provide a possibility to use a monitor adapted for a special cassette also with different conventional or special tube systems.
- 5.4 The problem is solved in accordance with Claim 1 by providing the system according to the preamble of Claim 1 with a cassettelike holder (cf. paragraph 3.2 above) by means of which the control function of the monitor is arranged to be transmitted to a conventional tube system when this is fixed to the monitor by means of the holder at the place intended for fixing the cassette.
- 5.5 The solution of the problem cannot be considered as being obvious to a person skilled in the art. Neither the prior art documents D1 to D5 nor the common general knowledge suggest the provision of a triple combination comprising a monitor, a cassette and a cassettelike holder which enables one and the same monitor adapted for a special cassette to be used with different conventional tube sets.

Having regard to the interpretation of the term "cassette" in paragraph 3.1 above, arrangement 11 depicted and described in document D4 corresponds to a cassette. In contrast to the opinion of the Appellant, the Board takes



the view that this cassette is not suitable to be used with different kinds of conventional tube sets, which can easily and simply be inserted into the cassette by the user of the blood treatment system. Indeed, Figure 4 of document D4 shows that arrangement 11 represents a cassette which is apparently assembled in advance, i.e. in the factory and not at the place of use, e.g. in hospital. This is supported by the statements in document D4, Claim 1, page 13, second paragraph, page 22, second paragraph and page 24, third paragraph. There are no means indicated in Figure 4 or 1 which would enable or facilitate the exchange of the tube system 16. Holder 18 forming part of arrangement 11 cannot thus be considered as a cassettelike holder or adapter into which different tube systems can be inserted in an easy manner.

In consequence, document D4 could not have given the skilled person a hint to provide a cassettelike holder or adapter between the monitor and the tube set such that the special monitor can also be used with different conventional tube systems easily to be fixed to the holder before use and the holder can carry out its intended function of transmitting the control functions of the monitor to any conventional tube system.

Similarly, document D5 would not have induced the skilled person to solve the above problem in the way set out in Claim 1. In particular, Figure 3 of this document shows that cassette 18 is adapted to house a special tube system and is not suitable to receive conventional tube systems of different kinds.

Documents D1 to D3 are even further remote from the subject-matter of Claim 1 than documents D4 and D5.

The argument that it might be common general knowledge to use an adapter-like system when adaptation to a variety of conditions is required, was not convincing in the present case in the total absence of such means in the numerous attempts to improve the capability of medical appliances.

Summing up, the Board comes to the conclusion that the provision of a cassette holder and thus the triple combination of a monitor, a cassette and a cassettelike holder cannot be derived in an obvious manner from the cited prior art and, accordingly, involves an inventive step having regard to Article 56 EPC.

6. The blood treatment system according to Claim 1 is, therefore, patentable (Article 52(1) EPC) and the patent may be maintained on the basis of Claims 1 to 9 as granted.

#### Order

For these reasons, it is decided that:

The appeal is dismissed.

The Registrar:



S. Fabiani

The Chairman:



G. Szabo

04743

