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**D E C I S I O N**  
**of 2 July 2002**

**Case Number:** T 0157/99 - 3.2.2

**Application Number:** 91105180.3

**Publication Number:** 0458041

**IPC:** A61M 1/14

**Language of the proceedings:** EN

**Title of invention:**

System for controlling a medical treatment, for example dialysis

**Patentee:**

GAMBRO AB

**Opponent:**

FRESENIUS AG

**Headword:**

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**Relevant legal provisions:**

EPC Art. 56

**Keyword:**

"Inventive step (no)"

**Decisions cited:**

-

**Catchword:**

-



Case Number: T 0157/99 - 3.2.2

**D E C I S I O N**  
**of the Technical Board of Appeal 3.2.2**  
**of 2 July 2002**

**Appellant:** FRESENIUS AG  
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**Respondent:** GAMBRO AB  
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**Decision under appeal:** Interlocutory decision of the Opposition Division  
of the European Patent Office posted 9 December  
1998 concerning maintenance of European patent  
No. 0 458 041 in amended form.

**Composition of the Board:**

**Chairman:** W. D. Weiss  
**Members:** M. G. Noël  
R. T. Menapace  
R. Ries  
J. C. M. De Preter

## Summary of Facts and Submissions

- I. By interlocutory decision dated 9 December 1998, the opposition division decided to maintain the patent in amended form. The state of the art was based, principally, on a prior use.

The first instance decided to disregard document D3 EP-A-0 208 090 (parent of US-A-4 728 496) because it did not disclose a powder vessel connected to fluid supplying means and document D2 EP-A-0 278 100 (parent of US-A-4 784 495) because it was suggested therein to remove the powder concentrate vessel and to connect instead a source of cleaning liquid for disinfection of the system. Therefore, it taught away from using a powder concentrate as cleaning agent for disinfection.

- II. The appellant (opponent) lodged an appeal on 9 February 1999 against the first instance decision and filed a statement of grounds within the prescribed time limit.

- III. In a communication of the Board dated 22 January 2002 sent following a summons to attend oral proceedings, the attention of the parties was drawn to documents D3 and D2 both cited in the application as originally filed, which were felt to be more relevant than the alleged prior use.

- IV. The respondent (patentee) replied by letters dated 2 and 26 June 2002 and filed each time amended claims.

- V. Oral proceedings were held on 2 July 2002 during which the discussion concentrated on the inventive step of the claimed subject-matter vis-à-vis the prior art documents D3 and D2. The final requests were as

follows:

The appellant requested that the decision under appeal be set aside and that the European patent be revoked.

The respondent requested that the appeal be dismissed and that the patent be maintained according to the decision under appeal (main request) or on the basis of claim 1 as filed on 26 June 2002, further dependent claims as granted (with the readiness to amend them when necessary).

VI. The parties argued as follows:

(i) The appellant

- Document D3 discloses an apparatus for the preparation of a treatment fluid such as a dialysis apparatus of the type presented in the precharacterising clause. The subject-matter of claim 1 (main request) differs therefrom by the insertion of a vessel containing a cleaning agent in powder form for the in line production of a cleaning fluid at the inlet of the fluid supplying means.
  
- Since the use of a vessel containing a powder concentrate for the preparation in line of a treatment fluid is known from document D2, the subject-matter of claim 1 is suggested by the combination of documents D3 and D2, considering that the use of a powder concentrate vessel in D2 is not restricted to the production of a treatment fluid but also applicable to the production of fluids in connection with other medical procedures

or treatments such as the production of flushing fluid for the cleaning of wounds.

- Claim 1 according to the auxiliary request only differs from the main request by the addition of connection means for connecting the vessel to the fluid supplying means. Such connection means are also known from document D2 and, therefore, fail to add an inventive step to the previous request.

(ii) The respondent

- Document D3 does not disclose the use of a vessel containing a powder concentrate for producing a treatment fluid. This document is only concerned with recirculating the heated fluid for disinfection or sterilization of the system through the same flow path as that used for producing the treatment fluid.
- Document D2 is confined to the production in line of a treatment fluid, the physico-chemical characteristics of which and the parameters for adjusting the apparatus are different from those for obtaining a cleaning fluid. At page 9 of document D2, it is stated that for disinfection or sterilization of the system the powder concentrate vessel must be removed and the remaining conduit connected instead to a source of disinfection liquid. This clearly teaches away from using a powder concentrate vessel for producing in line a cleaning fluid. The skilled person, therefore, would not be prompted to combine documents D3 and D2 and to arrive at the subject-matter of claim 1.

- Claim 1 according to the auxiliary request incorporates connection means so as to further structurally distinguish the claimed combination of the state of the art.

VII. The independent claims at issue read as follows:

Main request:

"A medical treatment apparatus intended for preparation and/or administration of a treatment fluid, for example an apparatus for dialysis, said apparatus comprising:

an inlet (1a) for introducing a fluid, preferably essentially water, into a conduit (1) of the apparatus, conditioning means (2 - 22) for preparing and/or controlling said fluid for forming said treatment fluid and/or for flowing said treatment fluid through a flow path of said apparatus;

connection means (36,37) for connecting the apparatus to a treatment device (33), for example a dialyser, for supplying said treatment fluid to said treatment device; and

introduction means (1,8;12,13;16,17) for introducing a cleaning fluid into said apparatus and for flowing said cleaning fluid along essentially the same flow path as the treatment fluid, except for said treatment device (33), for cleaning the apparatus; characterised by

a vessel (1', 1'', 1''') containing a cleaning agent in powder form, which achieves or at least aids said cleaning, said vessel being connected to supply means (1a) for supplying a solvent to said vessel whereby said solvent enters the vessel for mixing with said cleaning agent for dissolution and diluting of

said cleaning agent for forming said cleaning fluid and the vessel also being connected to the introduction means."

Auxiliary request:

"A medical treatment apparatus intended for preparation of a treatment fluid by dissolving at least one treatment concentrate in powder form and for administration of the treatment fluid, for example an apparatus for dialysis, said apparatus comprising: an inlet (1a) for introducing a fluid, preferably essentially water, into a conduit (1) of the apparatus, conditioning means (2 - 22) for preparing and/or controlling said fluid for forming said treatment fluid and/or for flowing said treatment fluid through a flow path of said apparatus; connection means (36,37) for connecting the apparatus to a treatment device (33), for example a dialyzer, for supplying said treatment fluid to said treatment device; and introduction means (1,8;12,13;16,17) for introducing a cleaning fluid into said apparatus and for flowing said cleaning fluid along essentially the same flow path as the treatment fluid, except for said treatment device (33), for cleaning the apparatus; said conditioning means including vessel connection means (44,45,46,47) for connecting a vessel containing said at least one treatment concentrate to the inlet (1a) and to the introduction means (1,8;12,13;16,17); characterized by a vessel (10f) containing a cleaning agent in concentrated powder form, which achieves or at least aids said cleaning, said vessel (10f) being connected via said vessel connection means (44,45,46,47) to the

supply means (1a) for supplying a solvent to said vessel (10f) whereby said solvent enters the vessel for mixing with said cleaning agent for dissolution and diluting of said cleaning agent for forming said cleaning fluid and said vessel (10f) being connected to the introduction means via said vessel connection means (44,45,46,47)."

### **Reasons for the Decision**

1. The appeal is admissible.
2. *Amendments*

The question whether there are any formal objections to the current version of the claims need not be answered since both claims 1 (main and auxiliary requests) are anyway unallowable on other grounds, as hereinafter explained.

3. *Main request*
  - 3.1 Document D3 represents the state of the art coming closest to the invention. It discloses all the precharacterising features of claim 1, namely a medical treatment apparatus intended for preparation and/or administration of a treatment fluid, for example an apparatus for dialysis, comprising essentially a conduit for introducing a fluid (water), means for controlling said fluid and for forming a treatment fluid flowing through a flow path, connection means for supplying said treatment fluid to a treatment device (dialyser) and means for introducing a cleaning fluid and for flowing it along the same flow path (except for



the dialyser) as the treatment fluid, for cleaning the apparatus.

It is to be noticed that the figure of document D3 is identical to Figure 1 of the present patent with the same reference signs for designating the same elements, with the exception of the plurality of vessels 1', 1'', 1''' which, in the patent, are additionally connected to the different fluid flow inlets. As also mentioned in the patent specification (column 1, lines 44 to 51), the apparatus disclosed in document D3 can, after certain amendments, be used for the application of the present invention.

In document D3 the fluid for disinfection or sterilization of the system is fed as a liquid into conduit 1 and heated in a heating device 2 to a temperature higher than the normal treatment temperature. In the simplest case (disinfection) the fluid is water, but it can be supplemented by chemical products to assure effective sterilization. In both cases, the heated fluid is recirculated in the system through a by-pass arrangement 34-43, also identical to that preferably used in the present patent.

The major difficulty with this known apparatus is that large quantities of the cleaning solution have to be prepared and held on stock for later use, which involves considerable logistic and conservation problems. Therefore the basic problem as stated in the patent in suit consists in simplifying the cleaning operation of such a medical treatment apparatus (see patent column 2, lines 11 to 18).

This problem is solved by the characterising features

of claim 1 according to which a vessel or cartridge 1', 1'', 1''' containing a cleaning agent in powder form is connected to the fluid supply means for mixing and dissolution of said powder cleaning agent for forming a cleaning fluid, whereby normal tap water is used for forming the cleaning fluid in situ and immediately before its introduction into the apparatus to be cleaned. The subject-matter of claim 1 differs from this disclosure of document D3 by its characterising features.

- 3.2 Document D2 discloses a system for the preparation of a medical treatment fluid, in particular a dialysis fluid, by dissolving a powder concentrate contained in a vessel inserted at the inlet of a solvent (water) supplying means (cf. e.g. cartridge 10 in Figure 6). The benefit of the arrangement disclosed in document D2 resides in its ability to prepare a concentrate fluid in line, i.e. directly at the point of treatment and at the time of use, thus avoiding the necessity of preparing beforehand large quantities of concentrate solutions and the associated problems of stability, precipitation and contamination (cf. page 3, lines 48 to 50; page 4, lines 9 to 11 and page 5, lines 11 to 15).

When the solvent enters the powder concentrate vessel, the mixing operation produces a substantially saturated solution by dissolving and diluting the powder concentrate (cf. page 6, lines 20 to 26 and 34 to 35). Moreover, the cartridge illustrated on Figure 7 of document D2 and the associated connection means for rapid connection and replacement of the cartridge, are rigorously identical to those shown in Figure 2 of the present patent. Therefore, the vessel disclosed in

document D2 is suitable to the application contemplated in the present invention, as also mentioned in the patent itself (cf. column 5, lines 25 to 28).

It results therefrom that document D2 discloses all the characterising features of claim 1, except the nature of the powder concentrate (cleaning agent) contained in the vessel. But as further mentioned in the patent specification (column 5, lines 28 to 30) the difference is solely that the cartridge shall contain a cleaning concentrate instead of a treatment concentrate. In the Board's view this minor difference relates to the use of the apparatus but fails to distinguish it structurally.

Further, the device disclosed in document D2 is intended to be used in connection with a treatment apparatus of the type disclosed in document D3 in which the same logistic problem arises in connection with the preparation of the treatment fluid as for the preparation of the cleaning fluid according to the patent in suit. Since the personnel performing the treatment of the patients is in most cases the same as the one performing the cleaning and sterilising operation after the treatment, they will immediately be aware that the solution to the problem which has been found in document D2 for the preparation for the treatment fluid can, with the same benefit, be used for the preparation of the cleaning fluid. The only modification which has to be applied to the apparatus according to document D3 is the provision of an adequate connection.

- 3.3 The Opposition Division concurred with the respondent that document D2 could not suggest the invention, since

for disinfection or sterilization of the system the vessel of powder concentrate had first to be removed for connecting, instead, a source of disinfection liquid via separate conduits 40, 42 (cf. Figure 6 and page 9, lines 24 to 30 and 45 to 48). A cartridge containing a cleaning agent, therefore, was not provided.

The Board cannot accept this argument since Figure 6 of document D2 only refers to a specific embodiment, which is overridden by the general teaching in this document and its possible applications. Thus, at the end of document D2 (page 13, lines 51 to 53) it is stated that the components included in the system may be varied within wide limits both with regard to their form and their function, which implicitly includes powder concentrates of any type such as for treatment or for cleaning purposes. Besides, the cartridge proposed in document D2 is perfectly suitable and can be used as it is, i.e. without modification. As also mentioned in the patent itself (column 1, lines 56 to 58), the system disclosed in document D2 can be used as such to produce a cleaning fluid as well.

Further, the system of document D2 is generally presented (page 3, lines 10 to 14: "Field of the invention") as a system usable in connection with other medical procedures or treatment such as, for example, the production of flushing fluid for cleaning of wounds. Not only this passage generally relates to the production of a cleaning fluid but it is also to be compared with the introductory part of the patent specification (column 1, lines 21 to 26) according to which the apparatus of the present patent can be used in connection with many other medical treatments so as

to produce, for example, a wound rinsing fluid which is considered, this time, as a treatment fluid. The above passages thus represent a link between document D2 and the present patent as both systems are equally suitable for producing a wound rinsing fluid and, therefore, perfectly interchangeable. The only modification is concerned with the vessel content, as already contemplated in point 3.2 above.

- 3.4 It results therefrom that 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. *Auxiliary request*

The subject-matter of claim 1 according to the auxiliary request differs from that of the main request by the incorporation, in both parts of the claim, of connection means for connecting the vessel to the fluid supplying means. Again, these connection means are known from document D2 as also mentioned in the present patent (column 5, lines 25 to 28), so that the incorporated features fail to add any inventive matter to the previous subject-matter. Consequently, the subject-matter of claim 1 according to the auxiliary request does not involve an inventive step, either.

**Order**

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

1. The decision under appeal is set aside.
2. The European patent is revoked.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß