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**Datasheet for the decision  
of 22 February 2008**

**Case Number:** T 1430/05 - 3.3.05

**Application Number:** 95911779.7

**Publication Number:** 0749345

**IPC:** B01D 25/00

**Language of the proceedings:** EN

**Title of invention:**

A filtration device for removal of leukocytes

**Patentee:**

PALL CORPORATION

**Opponent:**

Fresenius Medical Care Deutschland GmbH

**Headword:**

Flow restriction/PALL

**Relevant legal provisions:**

EPC Art. 101(3), 123, 56

EPC R. 100(1)

**Relevant legal provisions (EPC 1973):**

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**Keyword:**

"Examination of amendments (admissibility: yes)"

"Amendments extending beyond the content of the application as  
filed: - main request (yes) - auxiliary request (no)"

"Inventive step: auxiliary request (yes) - improvement over  
prior art"

**Decisions cited:**

T 0277/88, T 0922/94, G 0009/91

**Catchword:**

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Case Number: T 1430/05 - 3.3.05

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.05  
of 22 February 2008

**Appellant:** Fresenius Medical Care Deutschland GmbH  
(Opponent) Else-Kröner-Strasse 1  
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**Representative:** Thoma, Michael  
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**Respondent:** PALL CORPORATION  
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**Representative:** Hoeger, Stellrecht & Partner Patentanwälte  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
11 October 2005 concerning maintenance of  
European patent No. 0749345 in amended form.

**Composition of the Board:**

**Chairman:** G. Raths  
**Members:** J.-M. Schwaller  
C. Vallet

## Summary of Facts and Submissions

I. This appeal was lodged by the opponent against the interlocutory decision of the opposition division maintaining the European patent 0749345 in amended form on the basis of the set of claims 1 to 8 according to the first auxiliary request submitted and amended during the oral proceedings of 9 March 2005.

Independent claim 1 of this request (also claim 1 of the main request of the present decision) read as follows:

*"1. A biological fluid filtration system for filtering blood or a blood component comprising:*

*a biological fluid filtration means for filtering blood or a blood component including filtration elements (103) within said system and a chamber (108) for receiving a biological fluid comprising blood or a blood component to be filtered by said filtration elements;*

*an air vent means within said system, said vent means comprising a body having an inlet and outlet and at least one port (4) with at least one hydrophobic filter (3) thereon, and being operatively engaged to said biological fluid filtration means;*

*so that said biological fluid flows through said inlet into said body and through said outlet to said chamber under the effect of gravity;*

*the arrangement of the hydrophobic filter with respect to said outlet being such that during gravity fed*

*filtration, biological fluid contacts the hydrophobic filter and air ingress to the system via said vent port is prevented by a fluid pressure head greater than atmospheric pressure arising from a flow restriction means comprising a cross-sectional area downstream of said port, said cross-sectional area being less than the cross-sectional area of said inlet, and from operational engagement of the vent means to said filtration means whereby biological fluid is under pressure between said hydrophobic filter and said biological fluid filtration means; and*

*wherein air enters said port automatically when the supply of biological fluid flow stops thereby causing air to automatically enter into said port thereby draining biological fluid within said system."*

- II. The following document was *inter alia* relied upon during the opposition proceedings:

D1 = WO-A-91/17809

- III. In the contested decision, the opposition division considered that the above claim 1 met the requirements of Article 123 EPC, considering in particular that its subject-matter resulted from granted claim 1 in which the flow restriction means contributing to a fluid pressure head greater than atmospheric were defined. A basis for this definition of the flow restriction means was to be found in the original published application at page 7, line 27 to page 8, line 11. The opposition division also held that although the restriction 11 disclosed at page 7 (lines 28 and 29) of the original application related to a specific

embodiment wherein the restriction was situated at the outlet 2 of the vent means, it was evident from the wording of granted claims 1 and 3 ("said pressure head is created by a flow restriction located downstream of said port") and from the whole context of the opposed patent that the fluid pressure head in the vent means was the result of a flow restriction the cross sectional area of which was smaller than the cross-sectional area of the inlet to the vent means. It was the relation of the two cross-sectional areas that was the essential feature of the invention for creating the fluid pressure head and not the exact position of the restriction downstream of the vent port. In other words, the fluid pressure head was created due to the presence of the flow restriction and independently of the exact position of the flow restriction.

IV. In the grounds of appeal dated 16 February 2006, the appellant *inter alia* objected to above claim 1 under Article 100(c) in combination with Article 123(2) EPC.

V. With its reply dated 2 November 2006, the respondent *inter alia* pointed out that it did not consent to the introduction of the opposition ground according to Article 100(c) EPC at this stage of the procedure. It also filed an amended claim 1 (auxiliary request) reading as follows:

"1. A biological fluid filtration system for filtering blood or a blood component comprising:

a biological fluid filtration means for filtering blood or a blood component including filtration elements (103) within said system and a chamber (108) for receiving a

*biological fluid comprising blood or a blood component to be filtered by said filtration elements;*

*an air vent means within said system, said vent means comprising a body having an inlet and outlet and at least one port (4) with at least one hydrophobic filter (3) thereon, and being operatively engaged to said biological fluid filtration means;*

*so that said biological fluid flows through said inlet into said body and through said outlet to said chamber under the effect of gravity;*

*the arrangement of the hydrophobic filter with respect to said outlet being such that during gravity fed filtration, biological fluid contacts the hydrophobic filter and air ingress to the system via said vent port is prevented by a fluid pressure head greater than atmospheric pressure arising from a flow restriction means formed in the outlet of the air vent means, said flow restriction means comprising a cross-sectional area downstream of said port, said cross-sectional area being less than the cross-sectional area of said inlet, and from operational engagement of the vent means to said filtration means whereby biological fluid is under pressure between said hydrophobic filter and said biological fluid filtration means; and*

*wherein air enters said port automatically when the supply of biological fluid flow stops thereby causing air to automatically enter into said port thereby draining biological fluid within said system."*

VI. Oral proceedings before the board took place on 22 February 2008.

VII. The appellant's arguments can be summarised as follows:

Claim 1 (both requests) did not fulfill the requirements of Article 123(2) EPC, because there was no basis in the application as filed (i.e. in its version published as WO 95/24255) for the feature relating to the fact that the fluid pressure head greater than atmospheric pressure in the air vent means arose from a flow restriction means as defined in claim 1 and from operational engagement of the vent means to the filtration means. As to the location of the restriction means, it could also not be derived directly and unambiguously from the application as filed that the restriction means might be located elsewhere as in the outlet of the air vent means.

The problem to be solved by the subject-matter claimed was to provide for an alternative system to the one described in D1. As D1 already disclosed an automatic gas inlet, it would not be inventive for a person skilled in the art faced with the above problem to replace the fluid flow regulating devices therein disclosed by another technically equivalent one, for instance with a flow restriction located downwardly to the gas inlet of D1.

VIII. The respondent (patent proprietor) argued in essence as follows:

As the granted patent had not been challenged under Article 100(c) EPC, the introduction of this fresh

ground for opposition at this procedural stage is not admissible.

The amendments to claim 1 (main and auxiliary request) have a basis in the passage at page 6, line 9 to page 8, line 17 of the application as filed.

As regards the problem to be solved over D1, this is to be seen in the provision of a blood filtering system fitted with an automatic gas venting means functioning in a secure and reliable manner.

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

The respondent requested as a main request that the appeal be dismissed, and as an auxiliary request, that the decision under appeal be set aside and that the European patent be maintained in amended form on the basis of claim 1 as filed on 2 November 2006 and claims 2 to 8 as maintained by the interlocutory decision of 9 March 2005.

## **Reasons for the Decision**

1. *Admissibility of the ground of opposition under Article 100(c) EPC*

The respondent, considering that the above ground of opposition was a fresh one, requested the board to disregard it at this procedural stage.



The board observes that the granted patent had indeed not been challenged on the basis of Article 100(c) EPC, but claim 1 having been amended in the course of the opposition procedure and - as attested by the minutes of the oral proceedings held before the opposition division - the opponent having raised objections under Article 123 EPC against said amended claim 1, the question whether the amendments extended beyond the content of the application as filed had thus already been in the debate before the first instance.

In any case, even if this issue had not yet been debated before the first instance, as claim 1 of both requests on file contain amendments, it is not only legitimate but even mandatory to verify that the amendments do not contain subject-matter extending beyond the content of the application as filed. Article 101(3) EPC [2000] in conjunction with Rule 100(1) EPC [2000] confers wide powers upon the boards to consider objections under the EPC, pleaded or not pleaded, that may arise from an amendment of the claims as originally filed (see T 277/88, OJ EPO 1990, 292; T 922/94). See also G 9/91, OJ EPO 1993, 408, reason 19: "... in case of amendments of the claims ... in the course of ... appeal proceedings, such amendments are to be examined as to their compatibility with the requirements of the EPC (e.g. with regard to the provisions of Article 123(2) and (3) EPC)".

The board therefore decides to reject the respondent's request and to admit the issue of allowability of the amendments under Article 123(2) and (3) EPC into the appeal proceedings.

2. *Main request - Allowability of amended claim 1 under Article 123(2) EPC*
- 2.1 The question to be answered is whether the passage "*a fluid pressure head ... arising from a flow restriction*" is directly and unambiguously derivable from the application as filed.
- 2.2 In claim 1 of the granted patent, the fluid pressure head was defined as "*arising from operational engagement of the vent means to said filtration means*" whereby in present claim 1 it is defined as being "*greater than atmospheric pressure*" and "*arising from a flow restriction means comprising a cross-sectional area downstream said port, said cross-sectional area being less than the cross-sectional area of said inlet, and from operational engagement of the vent means to said filtration means*".
- 2.3 The board notes that in the excerpt relied upon by the appellant as constituting a basis in the application as filed for the above features, the sole passage dealing with a flow restriction reads as follows: "*Outlet section 2 includes restriction 11 forming an outlet of chamber 10, and tubing socket 12 extending from the restriction 11 into which a length of tubing 13 may be inserted. Restriction 11 is typically a long small diameter port which connects chamber 10 to tubing 13. The cross sectioned area of the restriction should be less than the cross sectioned area of the inlet to allow fluid flowing therethrough to fill chamber 10 and contact hydrophobic filter 3. Liquid to be filtered enters the vent filter 15 via tubing 14 and port 7 and exits via restriction 11 and tubing 13. The length and*

*diameter of restriction 11 depends upon viscosity of the liquid being filtered and should be sized so that liquid entering the in-line vent filter 15 through port 7 will back up and fill chamber 10. At this condition, the liquid in chamber 10 will be at a pressure head greater than atmospheric pressure and below the bubble point pressure of the hydrophobic filter 3." (see WO 95/24255; page 7, line 28 to page 8, line 11).*

2.4 The board observes that the above passage belongs to the detailed description of the air venting means represented schematically in Figure 1A and the restriction 11 is described therein as being formed in the outlet of chamber 10. Apart from this specific location for the restriction 11, no basis could however be found in the above passage, nor in the remaining parts of the application as filed for a flow restriction means in general as defined in claim 1 of the main request, i.e. a flow restriction means not exclusively located in the outlet of the air vent means.

2.5 Under these circumstances, the above amendment to claim 1 of this request is not considered allowable, as it contains subject-matter extending beyond the content of the application as filed, which is contrary to Article 123(2) EPC. This request is therefore not allowable.

3. *Auxiliary request - Allowability of amended claim 1 under Article 123 EPC*

3.1 Claim 1 of this request differs from claim 1 of the main request in that the flow restriction means is

defined as being "*formed in the outlet of the air vent means*".

3.2 The appellant argued that present claim 1 did not meet the requirements of Article 123(2) EPC, because in the application as filed it was disclosed that the fluid pressure head greater than atmospheric pressure in the vent means arose exclusively from the flow restriction means formed in the outlet of the air vent means, whereas in present claim 1 the fluid pressure head greater than atmospheric pressure was described as arising from both the flow restriction means and from operational engagement of the vent means to the filtration means.

3.3 The board observes that the passage in the application as filed mentioning that the "*liquid in chamber 10 will be at a pressure head greater than atmospheric pressure*" (see page 8, lines 9 and 10) is included in an excerpt which describes in detail a schematic representation of the in line vent filter 15 depicted in Figure 1A and in which said vent filter is reported as being "*useable as an air venting means in accordance with the principles of the present invention*" (see page 6, line 16 to page 8, line 24).

The above excerpt furthermore falls under the heading "Detailed description of the Preferred Embodiments" and is located immediately after an introductory passage reading: "*The liquid filtration device constructed in accordance with the principles of the present invention utilizes an air venting means operatively engaged to a fluid filtration means. One embodiment of the filtration apparatus constructed in accordance with the*

*principles of the present invention is shown in Figure 2, and its operation is depicted in Figures 3 and 4.*" (page 6, lines 8 to 15 of the application as filed).

As the above introductory passage directly and unambiguously relates to a liquid filtration device utilizing an air venting means **operatively engaged** to a fluid filtration means, and as the excerpt mentioned hereinabove describing in detail the air venting means of Figure 1A is not limited to a mere listing of structural device features, but also describes flow characteristics of the fluids passing therethrough, the board has no doubt that the air venting means described in the excerpt at page 6, line 16 to page 8, line 24 of the application as filed is to be construed as being operatively engaged to the filtration means.

- 3.4 Under these circumstances, it is clear for the skilled person reading the above excerpt that "the pressure head greater than atmospheric pressure" corresponds to the **cumulative** back-pressure generated by both the flow restriction means and the devices located downstream thereof, and thus that "the pressure head greater than atmospheric pressure" in the air vent means arises from the "flow restriction means formed in the outlet of the air vent means" **and** "from operational engagement of the vent means to said filtration means".

For the above reasons, the board can thus not accept the appellant's restrictive interpretation of the application as filed and is therefore not convinced that the subject-matter of claim 1 of this request violates the requirements of Article 123(2) EPC.

3.5 As the scope of protection conferred by the amended claims of this request has furthermore not been extended over that of the claims of the patent in suit, the requirements of Article 123(3) EPC are therefore also fulfilled.

4. *Auxiliary request - Novelty*

Novelty of claim 1 of this request was not disputed and as can be seen in the next point, the subject-matter of independent claim 1 distinguishes from the most relevant prior art document D1.

5. *Auxiliary request - Inventive step*

5.1 The patent in suit relates to a gravity feed liquid filtration device useable to filter blood and blood components.

5.2 The parties agreed that document D1 - which relates to methods and means for venting air and other gases entrapped in a blood processing system (see page 1, first paragraph) - represents the closest prior art to the subject-matter presently claimed.

5.3 The (blood) processing system as disclosed in claims 1 and 2 of D1 comprises:

- a first container;
- a second container communicating with the first container;
- a functional biomedical device interposed between the first container and the second container;

- a gas inlet disposed at the first container or between the first container and the functional biomedical device;
- a gas outlet disposed between the functional biomedical device and the second container.

The gas inlet preferably includes a microporous membrane in a housing. The microporous membrane may have both liquophobic and liquophilic layers or other structures which allow gas but not contaminants to enter the system. In a preferred embodiment, the microporous membrane is liquophobic, i.e. it is non-wettable (D1: page 13, lines 18 to 25).

Exemplary functional biomedical devices include a filter, such as a leukocyte depletion filter (D1: page 10, lines 19 to 21).

Exemplary configurations of the gas inlet device are shown in Figures 6A, 6B and 6C of D1. In these configurations, the gas inlet device is provided with a first leg 61 (as the blood inlet), a second leg 62 (as the blood outlet) and a third leg 63 in which is disposed the membrane.

As disclosed in D1, page 30, line 15 to page 31, line 24, in operation, the column of blood flows from the first container through the biomedical device toward the second container (also called satellite bag) and the gas ahead the column of blood is separated by means of the gas outlet. After opening a clamp located adjacent to the satellite bag, processed blood product will fill the satellite bag until the first container collapses. In order to recover the blood retained in

the system, ambient air or a sterile gas may enter the system through the gas inlet. If the gas inlet is manual, a closure is opened or a clamp is released. If the gas inlet is automatic, the pressure differential between the gas inlet and the satellite bag will cause the air or gas to flow through the system in order to recover the blood trapped in the elements upstream of the satellite bag.

For gas inlets with a configuration as shown in Figures 6A, 6B and 6C, the blood enters and leaves the device at first and second legs 61 and 62, respectively, and the blood pressure head vents the gas present in the third leg 63 through port 30.

- 5.4 As put forward by the respondent, the problem to be solved in the light of document D1 as the closest prior art might be seen in the improvement of safety and reliability of a system for filtering blood or a blood component fitted with an automatic gas venting means.
- 5.5 Bearing in mind that the "air vent means" defined in present claim 1 corresponds to the "gas inlet" in document D1, the proposed solution according to present claim 1 differs from D1 in that a flow restriction means is formed in the outlet of the air vent means, said flow restriction means comprising a cross-sectional area downstream of said vent port, said cross-sectional area being less than the cross-sectional area of the inlet of the vent means.
- 5.6 For the board, the problem defined under point 5.4 has been plausibly solved for the following reasons.



Although D1 describes the use of flow regulation devices in its blood processing system (page 24, lines 27 to 29), this document neither indicates where they should be located nor that the flow regulating devices were supposed to maintain a fluid pressure head greater than atmospheric pressure in the "gas inlet". Thus, even if in D1 a fluid flow regulating device were located downstream of the "gas inlet", there still would be no certainty in this situation that blood flowing through the system would contact the membrane and thus prevent air ingress to the system.

For these reasons, as argued by the respondent, the system according to D1 requires careful handling of the blood processing system by trained personnel if air ingress to the system is to be avoided.

In contrast, in the system according to claim 1, the flow restriction means formed in the outlet of the vent means generates a back-pressure which, when summed with the back-pressure arising from the operational engagement of the vent means to the downwardly located filtration means, provides in the air vent means for a total fluid pressure head greater than atmospheric pressure, with the consequence that the biological fluid (blood) contacts the hydrophobic filter and prevents air ingress to the filtration process, thus allowing the air vent means to run automatically without any external manual operation.

Accordingly, the operation of the air vent means being rendered independent of human alertness and human errors can thus be avoided. The elimination of any human intervention and of the risk of air ingress

renders in consequence the air vent means more reliable and safer in comparison to the "gas inlet" of document D1, which requires manual intervention. So, the improvement over the prior art is acknowledged.

The board therefore does not accept the appellant's argument that the problem to be solved by the subject-matter presently claimed would have to be seen in the provision of an alternative system to the one depicted in D1.

5.7 Concerning the obviousness of the subject-matter of present claim 1 as to the solution to the problem defined under point 5.4 *supra*, the appellant argued that since D1 already disclosed that the gas inlet could be automatic, it would not be inventive for a person skilled in the art faced with the above problem to replace the fluid flow regulating devices disclosed in D1 by another technically equivalent one, for instance by a flow restriction formed in the outlet of the "gas inlet" of D1.

5.8 The board cannot share the appellant's view for the following reasons.

The sole passage of D1 (see page 31, lines 7-18) dealing with an "automatic" gas inlet reads as follows: "In order to recover the very valuable blood product retained in the system, ambient air or a sterile gas may enter the system through gas inlet 13 or 23. If gas inlet 13 or 23 is a manual gas inlet, a closure is opened or a clamp is released; if the gas inlet 13 or 23 is **automatic**, the pressure differential between the gas inlet and satellite bag 17 or 27 will cause the air

or gas to flow through conduit 12 or 22, through biomedical device 14 or 24, and toward satellite bag 17 or 27. In the process, retained blood or blood product that is trapped in those elements during processing are recovered from those components and collected in satellite bag 17 or 27" (emphasis added).

The skilled reader of the above paragraph will note that the "automatic" function referred therein has nothing to do with the primary function of the automatic vent means presently claimed, which is to ensure a fluid pressure head greater than atmospheric pressure in the air vent means, with the consequence that the biological fluid contacts the hydrophobic membrane and prevents air ingress to the system.

In contrast, the "automatic" gas inlet according to D1 relates exclusively to the recovery of blood retained in the system by automatically causing air or gas to flow through the system.

The above paragraph does also not disclose the technical means necessary to render "automatic" the gas inlet, let alone that said means should be a flow restriction formed in the outlet of the vent means.

The fact that the filtration system has been simplified by removing all manual operable valves is not necessarily obvious because, in the present case, the invention does not lie in the mere automation of functions performed by human operators, but the skilled person took advantage of a specific location of the flow restriction means and of the interactivity thereof with the vent means, said location and said

interactivity being not derivable from any prior art document. Furthermore, realizing the required back-pressure defined in claim 1 is not the consequence of simplifying complex technology by automation, but the consequence of artful measures which are taken to obtain a pressure greater than atmospheric pressure and not derivable from the prior art. There is also no hint in D1 to remove the manually operated opening/closing devices, such as clamps or valves, and to design the blood processing system therein described so as to obtain automatically, i.e. without manual intervention, a pressure head greater than atmospheric.

Under these circumstances, the board considers that any lack of inventive step argumentation based on D1 in order to arrive at the subject-matter of present claim 1 would only be based on hindsight, which is not allowable.

5.9 The remaining documents cited during the opposition proceedings were not relied upon by the appellant at the appeal stage. In the board's judgment, they do not contain further information which would point towards the claimed solution of the problem stated above.

5.10 Accordingly, for the reasons indicated above, the subject-matter of claim 1 cannot be considered as being obvious to a person skilled in the art in view of the cited prior art and therefore involves an inventive step.

As claims 2 to 8 represent particular embodiments of the subject-matter of claim 1, they derive their patentability from claim 1 on which they depend, and

thus the set of claims according to the auxiliary request meets the requirements of Article 56 EPC.

## **Order**

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

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent in amended form on the basis of claim 1 filed on 2 November 2006 and claims 2 to 8 as maintained by the interlocutory decision of 9 March 2005, and a description to be adapted.

The Registrar:

The Chairman:

S. Sánchez Chiquero

G. Rath