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**D E C I S I O N**  
**of 8 September 2005**

**Case Number:** T 0598/03 - 3.2.2

**Application Number:** 97122051.2

**Publication Number:** 0856319

**IPC:** A61M 1/02

**Language of the proceedings:** EN

**Title of invention:**

Device and method for processing blood for human transfusion

**Patentee:**

PALL CORPORATION

**Opponent:**

FRESENIUS BIOFIL S.R.L.

**Headword:**

-

**Relevant legal provisions:**

EPC Art. 56

**Keyword:**

"Inventive step (no) "

**Decisions cited:**

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**Catchword:**

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Case Number: T 0598/03 - 3.2.2

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.2  
of 8 September 2005

**Appellant:** Fresenius Biofil s.r.l.  
(Opponent) Via Canalazzo, 13/z  
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**Respondent:** PALL CORPORATION  
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**Representative:** Hoeger, Stellrecht & Partner  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
4 April 2003 concerning maintenance of European  
patent No. 0856319 in amended form.

**Composition of the Board:**

**Chairman:** T. Kriner  
**Members:** M. Noel  
E. Dufrasne

## Summary of Facts and Submissions

- I. By interlocutory decision dated 4 April 2003, the opposition division decided to maintain the European patent No. 0 856 319 in an amended form.
- II. The appellant (opponent) lodged an appeal, the notice of which was received at the EPO on 23 May 2003, against the first instance's decision. The appeal fee was paid at the same date and a statement setting out the grounds of appeal was filed by a letter dated 12 August 2003 and received at the EPO on 14 August 2003, bearing the name of Fresenius Medical Care AG.
- III. In a communication dated 1 September 2003, the Board noted that, though the notice of appeal had been filed in the name of the opponent, Fresenius Biofil srl, the statement setting out the grounds of appeal was filed by the representative of the appellant, in the different name of Fresenius Medical Care AG. The Board requested explanations thereon from the appellant.
- IV. In its reply dated 11 November 2003, the appellant explained that there had been no transfer or even change of name of the appellant. It further pointed out that all other references apart from the name associated with the statement of grounds of appeal were accurate. Therefore, the appellant requested correction of the erroneous name mentioned with the statement of grounds of appeal.
- V. In its letter dated 23 December 2003, the respondent expressed the contrary opinion that the letter in the name of Fresenius Medical Care AG must be interpreted

as filed by a third party submitting arguments, that no statement setting out the grounds of appeal had been filed in due time by the appellant and that, consequently, the appeal was inadmissible.

- VI. In a second communication posted 26 April 2005, the Board expressed its preliminary opinion that it was satisfied with the answer provided by the opponent, and that it intended to allow the correction and to consider the appeal admissible.

It further informed the parties of its preliminary opinion concerning the patentability of the claimed subject-matter vis a vis the cited state of the art.

- VII. Oral proceedings were held on 8 September 2005 during which the admissibility of the appeal and the patentability of the subject-matter of independent claim 1 were discussed.

- VIII. At the end of the oral proceedings the requests of the parties were as follows:

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

The respondent (patentee) requested that the appeal be dismissed and that the patent be maintained in the version as filed during the oral proceedings of 17 March 2003 before the opposition division.

IX. Independent claim 1 reads as follows:

"Use of a device for the collection and processing of human blood comprising a first container (11) and at least one second container (13) connected thereto, wherein a leucocyte filter (14) comprising a synthetic fibrous medium having a Critical Wetting Surface Tension (CWST) of at least 70 dynes/cm is interposed between the first container (11) and the second container (13), the leucocyte filter (14) permitting platelet-rich-plasma to pass therethrough and depleting leucocytes therefrom, in the preparation of leucocyte-depleted platelets for storage."

X. The following documents have been considered by the Board and are referred to in the present decision:

D7: EP-A1-0329303 (US priority 4 880 548)

D8: "Alloimmunisation to HLA Antigens following Transfusion with Leucocyte-Poor and Purified Platelet Suspensions", M. Fisher et. al, Vox Sang. 49: pp 331-335 (1985)

P1: "Importance of White Blood Cells in Platelet Storage", J. L. Gottschall et. al, Vox Sang. 47: pp 101-107 (1984)

P3: "In vitro Evaluation of a New Filter for Leucocyte Depletion of Platelet Concentrate during Component Preparation", L. D. Christensen et. al, Vox Sang. 67: pp 267-271 (1994).

XI. The following substantive arguments were submitted by the parties:

(i) The appellant

The separating device according to document D7 produced leucocyte-depleted platelets by using a synthetic leucocyte filter having a Critical Wetting Surface Tension (CWST) in the range as claimed. It was, therefore, suitable for preparing leucocyte-depleted platelets for storage even if a storage was not specifically mentioned in this document.

Besides, the general considerations on the storage of leucocyte-depleted platelets as set out on paragraph 30 of the contested patent related to the state of the art, not to the invention. Moreover, the relaxation of the storage life over a period of five days resulted from the removal by filtration of the skin disc of the donor, not of contaminating leucocytes. Therefore, the storage of leucocyte-depleted platelets was not originally an object in the patent in suit.

Document D8 disclosed the use of an Immugard IG 500 cotton filter for the further purification of a platelet-rich-plasma (PRP) suspension, thereby depleting leucocytes up to a content of  $<5 \cdot 10^6$  per transfusion, which was also considered as an inducement towards the storage of high quality platelets.

The subject-matter of claim 1 was, therefore, obvious, when considering the use of a suitable filtering device such as in D7 for filtering a PRP suspension, as suggested by D8.

(ii) The respondent

Document D7 did not mention any storage of the produced leucocyte-depleted platelet concentrate because the device described therein was provided to be used at bed side, i.e. just before administration of platelets to a patient, whereas the device according to claim 1 in suit was specifically intended for the preparation of leucocyte-depleted platelets for storage. As indicated on paragraph 30 of the patent, removal of leucocytes from the platelet concentrate permitted the five days storage life of the platelets to be relaxed.

Document D8 disclosed the use of an Immuguard IG500 cotton wool filter which removed over 25% of platelets during filtration. This filter, therefore, was not appropriate to the invention. As to the storage issue, D8 referred to document P1 (identified as reference [11]), which recommended using slow centrifugation instead of filtration to deplete leucocytes from the platelets suspension, prior to storage, in order to improve the quality of the platelets. Also document P3 warned against a possible drawback of pre-storage leucocyte-depletion due to in vitro activation of the platelets during filtration.

Since, therefore, none of the prior art documents would have induced the skilled person to use the filtration technique for platelet preparations which were to be stored prior to the administration to a patient, the subject-matter of claim 1 was not obvious.

## Reasons for the Decision

### 1. *Admissibility*

The respondent disputes the admissibility of the appeal, the arguments presented with the letter dated 12 August 2003 having been filed in the name of Fresenius Medical Care AG, i.e. by a third party, and as a consequence no statement setting out the grounds of appeal having been filed in due time by the appellant.

Rule 88, first sentence, EPC allows correction, on request, of errors of transcription and mistakes in any document filed with the EPO. The further requirement according to Rule 88, second sentence, EPC, that the correction must be obvious only applies to corrections in the description, claims or drawings.

It is established by the Boards of Appeal that a correction substituting the name of the applicant is allowable under Rule 88, first sentence, EPC. The second sentence of Rule 88 EPC not being applicable, it is sufficient for these purposes to establish that a mistake has been made, what the mistake was and what the correction should be (J 18/93, OJ EPO 1997, 326, J 17/96 of 3 December 1996, not published in the OJ EPO and J 31/96 of 25 November 1997, not published in the OJ EPO).

Closer to the present case, decision T 814/98 of 8 November 2000 (not published in the OJ EPO) allowed under Rule 88, first sentence, EPC the correction of the name of the appellant in the notice of appeal, the



mistake being established and its correction allowed on the basis of all other accurate elements in the notice of appeal.

In the present case, if it is established that the letter dated 12 August 2003 is in the name of Fresenius Medical Care AG, that letter was sent by the representative of the appellant, under the same internal references and correctly referred to the patent number, patent title and appeal case. Moreover, the letter starts with: "Die am 22. März 2003 erhobene Beschwerde wird folgendermaßen begründet:...".

On the other hand there is no element in the letter concerned or anywhere else in the file which would support any intention of the appellant to have the appeal filed in the name of some other natural or legal person other than the opponent (distinguishing from decision T 298/97, OJ EPO 2002, 83).

On the basis of these elements, the Board holds that it has been convincingly established by the appellant that a mistake occurred in the name mentioned in the letter filed with the statement of grounds of appeal and that sufficient elements are provided in order to allow its correction.

Therefore, the Board allows under Rule 88, first sentence, EPC the correction of the name of the appellant from Fresenius Medical Care AG to Fresenius Biofil SRL in the letter dated 12 August 2003 comprising the statement of grounds of appeal.

The appeal thus complies with Articles 106 and 108 and Rule 64 EPC and is admissible.

2. *Inventive step*

2.1 D7 represents the closest prior art document in view of most structural and functional similarities with the subject-matter of claim 1 in suit. D7 is also taken as starting point in the patent application (in the form of its US priority No. 4880548) and constantly referred to in the patent specification (see paragraphs 11, 18, 21, 30, 37, 44, 45 and 47).

2.1.1 As specified in the contested patent (paragraphs 19 to 21) the leucocyte filter used in the invention is made of a synthetic fibrous medium having a critical wetting surface tension (CWST) range of 70 to 115 dynes/cm, i.e. at least 70 dynes/cm as actually claimed. A synthetic filter having a similar CWST range of 73 to 115 dynes/cm and having been modified by applying the same surface treatment ( $\gamma$ -radiation grafting) in order to improve the fiber surface characteristics, was already used in D7 (see page 6, lines 52-54; page 9, lines 9-17 and from page 11, line 47 to page 12, line 4). A minor discrepancy of 3 dynes/cm on the minimum value of the range can be neglected compared to the large extent of the range.

The filter of the D7 device is disposed across the fluid flow path and generally serves to separate undesirable substances such as leucocytes from a suspension of platelets in blood plasma (D7, page 12, lines 54-56). Two containers are, therefore, implicitly

provided for containing the fluids before and after the separation.

2.1.2 In the last portion of claim 1 in suit, the term "permitting" is ambiguous in the sense that the following feature can be regarded as optional, i.e. as a mere possibility of depleting leucocytes from platelet-rich-plasma in the preparation of leucocyte depleted platelets. Since D7 makes use of a similar filter for producing a leucocyte-depleted platelet concentrate, which is another form of leucocyte-depleted platelets, the claimed feature mentioned above is not clearly distinguished from the disclosure of document D7.

As a matter of fact, leucocyte depletion is achieved in D7 by filtering a platelet concentrate (PC) and in the contested patent by filtering a platelet-rich-plasma (PRP) suspension, using the same filtering medium. This results clearly from the comparative analysis presented in the introductory part of the present patent (paragraphs 11-13). More specifically, as set out both in the patent (paragraph 3, steps 1 to 6) and in D7 (page 2, lines 4-12) the conventional procedure of separation of donated whole blood into its various components comprises, after collection of the blood, two centrifugation steps followed each by an extraction (transfer) step. The PRP suspension is obtained after the first centrifugation-extraction step and the PC (platelet concentrate) after the second centrifugation-extraction.

Unlike document D7 in which leucocyte-depletion by filtration is performed on the PC, in the present

patent the filtration of leucocytes occurs on the PRP suspension after the first centrifugation, for all the advantageous reasons set out in the patent (paragraphs 11-13). In particular (paragraph 12) "one of the advantages of the devices and methods of this invention is that much better recovery is obtained when platelets are leuco-depleted in the form of PRP, compared with PC". It should be noted here that a second centrifugation is also provided in the procedure according to the present patent, but after the PRP filtration (see paragraph 17).

It results therefrom that both the patent and document D7 provide for leucocyte-depleted PC but with a different quality since the steps are performed in a different order. However this difference does not emerge from the use of the device as worded in claim 1.

- 2.1.3 In the last feature of claim 1 the expression "for storage" expresses only a purpose or the mere intention of the user and is more related to the use of the product than to the use of the device itself. The inventive contribution of this feature, therefore, can hardly be recognised.

The ability to store leucocyte-depleted platelets is principally given by an acceptable level of efficiency, i.e. less than  $10^7$  leucocytes per unit of PC, which corresponds, according to the patent (paragraphs 10 and 29) to a leucocyte depletion in excess of about 99,9%. Since the same level of leucocyte depletion is also required and obtained in D7 (see page 3, lines 31-35 and tables 2 to 11 ("Efficiency for unit passed")), the product obtained in D7 after filtration is *prima facie*

also suitable for storage, within the meaning of the present patent.

It is true that D7 does not expressly mention that the product should be stored before being administered to a patient. On the contrary, it is preferably used at bed side (page 23, last paragraph). However, having regard to the high level of efficiency provided, as mentioned above, a storage of the leucocyte-depleted preparation is not excluded. Further, it should be noted that also in the contested patent (paragraphs 11 and 30, items (d) and (e)) the general considerations presented in relation to the storage of PC may be addressed just as well to the prior art as to the invention. In fact, the above cited paragraphs are confined to declare that the storage of PC prior to removal of leucocytes or other source of bacterial growth, such as skin discs, should be avoided, but without considering the storage of leucocyte-depleted platelets as a requirement.

Therefore, the very last feature of claim 1 also fails to distinguish its subject-matter from the disclosure of document D7.

2.2 Even if claim 1 were to be construed according to the second alternative in which a suspension of platelet-rich-plasma is effectively passed through the filter in the preparation of leucocyte-depleted platelets for storage, the subject-matter of claim 1 would still be lacking in inventive step with respect to the combination of documents D7 and D8.

2.2.1 Document D8 which was submitted with the statement of grounds of appeal, relates to a careful preparation of

platelets in order to avoid transfusion of significant numbers of leucocytes. From D8 it is already known that the separation of pure platelets from donor blood was difficult since differential centrifugation tended to lead to moderate leucocyte contamination, whereas the alternative of filtration through most available filters led to loss of high proportions of platelets (page 331, paragraph bridging left and right columns).

D8 discloses the preparation of pure platelet suspension ( $<5 \cdot 10^6$  leucocytes) by filtering a PRP suspension obtained after collection and a first centrifugation, a procedure on which the present patent is based. But the Immugard IG 500 cotton wool filter which is used in document D8 would not be suited to the present patent since a great number of platelets are retained. In order to compensate for over 25% platelet loss during filtration, the volume of the plasma containing platelets suspension must be increased accordingly (page 332, left column).

- 2.2.2 On the other hand, the skilled person already knew from D7 (page 10, lines 50-56) that natural fibers such as cotton were not appropriate for the manufacturing of leucocyte removal devices because of a too high hold-up volume and, consequently, a poor platelet recovery. Therefore, the skilled person would logically have proceeded further with the synthetic filter of D7, which is perfectly appropriate for leuco-depleting a platelet suspension, and would have been directly induced by D8 to filter a less concentrated PRP suspension with the view to provide a higher yield of better quality platelets.

2.2.3 The considerations reported in D8 (page 334, third paragraph) about the consequences of leucocyte contamination on the quality of the stored platelets were already generally known from the state of the art, as mentioned in point 2.1.3 above, which is also confirmed by document P1 identified in D8 under the reference [11] (see in particular in P1, last paragraph of the abstract and page 107, last paragraph). For the assessment of the inventive step of the claimed subject-matter it is of no consequence that in P1 slow centrifugation is recommended instead of filtration, because the skilled person would in all probability start from D7, in which filtration has already been used as a preferred leucocyte-depletion technique. Taking account of the high level of efficiency reported in D8, the leucocyte-depleted platelet preparation obtained therein renders the product also suitable for storage within the meaning of the present patent.

Document P3 submitted by the respondent as evidence of possible drawbacks of pre-storage for the provision of leucocyte-depleted platelet concentrates could not have dissuaded the skilled person from storing leucocyte-depleted platelets obtained in D8, since document P3 was published already well after the filing date of the contested patent and, therefore, is not to be considered.

2.3 For all the foregoing reasons the subject-matter of claim 1 does not involve an inventive step within the meaning of Article 56 EPC. Since the European patent cannot be maintained partially it has to be revoked.

**Order**

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

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

The Registrar:

The Chairman:

V. Commare

T. Kriner