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D E C I S I O N
of 6 October 2005

Case Number: T 1117/03 - 3.3.05

Application Number: 92900488.5

Publication Number: 0556303

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Language of the proceedings: EN

Title of invention:
System and method for processing biological fluids

Patentee:
PALL CORPORATION

Opponent:
MACO PHARMA

Headword:
Biological fluid processing/PALL

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step: yes"

Decisions cited:
-

Catchword:
-

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Case Number: T 1117/03 - 3.3.05

D E C I S I O N
of the Technical Board of Appeal 3.3.05
of 6 October 2005

Appellant: (Opponent)	MACO PHARMA Rue Lorthiois F-59420 Mouvaux (FR)
Representative:	Derambure, Christian BREESE DERAMBURE MAJEROWICZ 38, avenue de l'Opéra F-75002 Paris (FR)
Respondent: (Proprietor of the patent)	PALL CORPORATION 2200 Northern Blvd. East Hills New York 11548 (US)
Representative:	Hoeger, Stellrecht & Partner Patentanwälte Uhlandstrasse 14 c D-70182 Stuttgart (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 3 June 2003 rejecting the opposition filed against European patent No. 0556303 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: M. Eberhard
Members: B. Czech
J. Willems

Summary of Facts and Submissions

I. The appeal is from the decision of the opposition division rejecting the opposition against European patent No. 556 303.

II. The patent was granted with four independent claims reading as follows:

"1. A biological fluid processing system of the kind comprising a first container (11) and a second container (41) and a third container (18), the first container (11) being in fluid communication with the third container (18), a porous medium (17) being interposed between the first container (11) and the third container (18), the porous medium (17) comprising a leucocyte depletion medium, the second container (41) being in fluid communication with the first container (11), characterized in that a further porous medium (12,13) is interposed between the first container (11) and the second container (41) in a closed system, the further porous medium (12,13) comprising a leucocyte depletion medium, or a combined leucocyte depletion and red cell barrier medium."

"21. A method for processing a biological fluid in a closed system including a porous medium (17) and a further porous medium (12,13) comprising separating the biological fluid into a supernatant layer and a sediment layer; passing the supernatant layer of the biological fluid through the further porous medium (12,13) in the closed system, the further porous medium (12,13) comprising a leucocyte depletion medium, or a combined leucocyte depletion and red cell barrier

medium and passing the sediment layer of the biological fluid through the porous medium (17) in the closed system, the first porous medium comprising a leucocyte depletion medium."

"31. A biological fluid processing system of the kind comprising a first container (11) and a second container (41) and a third container (18), the first container (11) being in fluid communication with the third container (18), a porous medium (17) being interposed between the first container (11) and the third container (18), the porous medium (17) comprising a leucocyte depletion medium, the second container (41) being in fluid communication with the first container (11), a red cell barrier medium (12,13) being interposed between the first container (11) and the second container (41) in a closed system."

"51. A method for processing a biological fluid comprising separating the biological fluid into a supernatant layer and a sediment layer; passing the supernatant layer of the biological fluid through a red cell barrier medium (12,13) in a closed system and passing the sediment layer of the biological fluid through a porous leucocyte depletion medium."

III. Ten references were cited in the course of the opposition proceedings, including the following prior art documents:

D1: US-A-4 596 657
D2: EP-A-0 370 584
D3: US-A-4 880 548
D4: US-A-4 925 572

D6: EP-A-0 349 188

D8: US-A-4 851 126

IV. In the contested decision, the opposition division concluded that the patent fulfilled the requirement of Article 83 EPC. Discussing in particular documents D1, D2 and D6 in detail, it also held that the subject-matter of all the claims of the patent as granted was novel and inventive in view of the cited prior art.

V. In its statement of grounds of appeal, the appellant (opponent) cited three new documents:

D11: J. L. Gottschall et al., "Importance of White Blood Cells in Platelet Storage"; Vox Sang., 47 (1984), pages 101-107

D12: Glossaire de la Transfusion Sanguine, 3e édition, 1987, pages 41 and 107

D13: EP-A-0 267 286

Referring to these documents and also to D3, D4 and D8, the appellant essentially argued that the claimed subject-matter lacked the required inventive step in view of a combination of D1 with D2.

VI. In its reply, the respondent (proprietor of the patent) maintained that the present invention was not obvious in view of D1 and D2, even when considering the disclosures of D11 to D13.

VII. Oral proceedings took place on 6 October 2005.

VIII. The essential arguments of the parties can be summarised as follows:

Lack of inventive step was the sole ground of opposition invoked by the appellant, who agreed with the respondent in that the disclosure of D1 was to be considered as the closest prior art. The appellant acknowledged that D1 did not disclose a further leukocyte-depleting filter for the filtration of the platelet rich plasma ("PRP" hereinafter) obtained after centrifugation of the whole blood.

Concerning the first alternative covered by claims 1 and 21 (leukocyte depletion only, no mandatory red cell barrier) the appellant argued as follows. D1 disclosed a closed system of four bags in fluid communication (Figure 1) with each other, which represented the closest prior art. D1 aimed mainly at providing a red cell concentrate having an extended storage life. For this purpose, a leukocyte depleting filter was arranged between the primary bag 12 and the further bag 16 for receiving red blood cell concentrate. In D1 it was also envisaged to separate and store other blood components, such as plasma and a platelet concentrate ("PC" hereinafter) in further bags of the closed system. D1 did not disclose a further leukocyte-depleting filter arranged between the primary bag and another bag. At the oral proceedings, the appellant emphasised that due to their broad wording claims 1 and 21 covered, but were not restricted to systems and methods for the separation of whole blood by centrifugation into a supernatant platelet-rich plasma ("PRP" hereinafter) and a sediment consisting of packed red cells ("PRC" hereinafter), with subsequent leukocyte-depletion of

these two products. Such an embodiment was described in the patent but it was not inventive. In view of the broad wording of the claims, the technical problem would consist in providing a further leukocyte-depleted product in a further bag of a closed system. It was generally known since 1970 that it was highly desirable to deplete leukocytes from any type of blood fraction before its use for transfusion. From D11, a document illustrating the common general knowledge, it was moreover apparent that it was desirable to deplete leukocytes from media containing platelets before their storage in order to avoid a loss of quality of the platelet product during storage. D11 would have given the skilled person an incentive to carry out the leukocyte depletion of a PRP as soon as possible and before storage, i.e. immediately after the centrifugation of the whole blood. As confirmed by D2, the skilled person knew that leukocyte removal from platelet containing suspensions could be done by centrifugation or, preferably, by filtration. D2 taught such a leukocyte filtration from platelet containing suspensions between two receptacles in a closed system. D3 (column 3, lines 47 to 50) confirmed that filtration was the preferable method. Prompted by its general knowledge as illustrated by D11, the skilled person would thus have combined the teachings of D2 and D1. More particularly, it would have arranged the leukocyte filter described in D2 between bag 12 and one of the further bags 14 or 26 of the system shown in Figure 1 of D1, which both could be considered as the "*second container*" within the meaning of claim 1 of the contested patent. In its view, the teaching of D2 was not restricted to the filtration of PCs, but also encompassed the filtration of platelet suspensions such

as PRP. This was confirmed by the explicit reference, in D2, to example 10 of D13, a document relating to the leukocyte filtration from platelet concentrates or suspensions. Since this example 10 related to the filtration of a PRP rather than of a PC, the most favourable results in terms of leukocyte removal and platelet passage as explicitly reported in D2 would encourage the skilled person to apply the teaching of D2 to the PRP obtained according to D1. In order to provide leukocyte depleted platelets using the system of D1 the skilled person only had the choice between filtering the PRP and filtering the PC. Even assuming that a combination of D1 and D2 led to a different system, this difference would not have implied any inventive step.

Having regard to the second alternative covered by claim 1 ("combined leucocyte depletion and red cell barrier medium"), the appellant argued in writing that D3 disclosed a leukocyte-depleting filter which was also suitable for eliminating red blood cells. Hence the skilled person, having obtained a system according to the first alternative, of claim 1, would have obviously chosen the filter of D3 and thereby obtained a system according to the second alternative.

Claim 21 concerned a process corresponding to the product features of claim 1. Therefore, for the same reasons as those given with respect to claim 1, this claim was not based on an inventive step.

Concerning claims 31 to 60 the appellant argued in writing that, due to their analogy with claims 1 to 20

and 21 to 30, they had to be revoked for the same reasons on the ground of lack of inventive step.

The respondent argued that the only straightforward and sensible understanding of the wording of claim 1 was that the first and second containers had to be in direct fluid communication, i.e. with no interposed further containers. The system could of course comprise more than just the three containers referred to, but not between the first and second containers. The possibility of having a further container therebetween, if it was to be covered, would have to be specifically indicated in the claim.

Concerning inventive step, the respondent argued that although claim 1 was very broad, it had not been shown that its subject-matter was obvious in view of some particular prior art. None of the documents cited by the appellant, taken in combination with the closest prior art as disclosed by D1, provided any information leading to the claimed systems and methods of claims 1, 21, 31 and 51. None of these documents contained any indication of a multiple-bag, two-filter system that can be assembled once to allow for two centrifugation steps and for obtaining only leukocyte depleted blood products.

The respondent considered that D2 essentially related to a separate system for the removal of leukocytes from previously stored platelet concentrates. D2 did not contain explicit information concerning the steps performed previously to obtain the platelet suspension to be treated. The teachings of D1 and D2 could be combined in a straightforward manner without having to

modify the systems of D1 and D2 by taking bag 14 of D1 as the starting storage bag according to D2. This combination of the two teachings was however more complex to perform than the claimed invention and required an additional bag. Moreover, when performed on a bag of PC obtained according to D1, the separated plasma fraction still contained leukocytes. Therefore, even assuming that D2 was also concerned with filtration of PRPs less concentrated in platelets, it did not suggest the arrangement of a leukocyte-depleting medium in the tubing through which PRP was expressed from the primary bag 12 of the system shown in D1, Figure 1. Therefore, without hindsight considerations, a combination of D1 and D2 did not lead to a system according to claim 1 in an obvious manner. D6 suggested filtering leukocytes from donated whole blood before its further separation in order to avoid the risk, expressly associated with the systems according to D1, of destroying the bag and filters during centrifugation. In view of D6, the skilled person would avoid increasing this type of risk by incorporating a further filter into the system of D1. D11 recommended the separation of leukocytes from platelet concentrates before storing the latter for several days, but it did not teach that this needs to be done immediately after the centrifugation of the whole blood, i.e. within several hours. Moreover, D11 was silent about the use of filters and did not teach in the direction of the present invention.

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

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appellant has not maintained the objection under Article 100(b) EPC that it had raised in the opposition proceedings. The board also sees no reason for questioning the positive finding of the opposition division concerning this issue.

2. The claimed subject-matter is novel with respect to the disclosure of the documents cited by the appellant. Since this was not disputed by the appellants, a detailed reasoning needs not to be given. Differences between the prior art and the claimed subject-matter emanate from the following discussion of inventive step.

3. Claim 1 refers to a system **comprising** three containers, designated as first, second and third container, respectively. More particularly, it is indicated in claim 1 that "**the** second container (41)" is "in fluid communication with **the** first container (11)", and that a "further porous medium (12,13) is interposed between **the** first container (11) and **the** second container (41) in a closed system" (emphasis added by the board).

3.1 In view of the use of the term "comprising", claim 1 is not strictly limited to systems with three containers. However, claim 1 refers to the first and second containers using the definite article "the" and specifies that these two containers are "in fluid communication". Moreover, the claim expressly mentions a further element interposed in the said flow path, i.e. the "further porous medium (12,13)".

3.2 In view of this particular claim wording, and in the context of the patent as a whole claim 1 is not considered to cover embodiments having one or more further containers in the flow path between the first container and the second container. Upon proper reading of claim 1, a container (such as container 42 in Figure 1 of the patent in suit) arranged further downstream of the second container (position 41 in Figure 1 and in claim 1), and thus being in fluid communication with the first container (position 11 in Figure 1) only through another intermediate container, is thus not to be considered as "the second container" in the sense of claim 1.

Inventive step

4. *Closest prior art*

4.1 Document D1 relates to a multiple bag closed system for collecting donated blood and separating it into several blood products. Upon use of the system, the donated blood is received in a first "primary" bag ("12") wherein it is centrifuged and separated into a PRC fraction and a supernatant platelet-containing plasma fraction. The latter is expressed into a second "satellite" bag ("14") connected to the first bag by means of a tubing. The red cells are then transferred into a third "satellite" bag ("16") via a further tubing and a leukocyte depleting fibrous filter medium ("26"). From the expressed PRP, plasma and PC may be obtained in respective bags. It is also generally stated in D1 that "the bag system 10 may optionally be equipped with other satellite bags into which other

blood components may be expressed or processed as necessary or desired". See in particular Figure 1; claims 1, 4, 5; column 2, lines 59 to 68 and column 3, lines 42 to 63.

4.2 Considering the constructional similarities of the device disclosed in D1 and the system of claim 1, and the fact that D1 also addresses the leukocyte removal from a blood product by means of filtration in a closed system, the board can accept the parties' view that the disclosure of D1 represents the closest prior art.

4.3 It was common ground between the parties that the only feature of the system of claim 1 of the patent in suit which was not disclosed in D1 was the provision of a further porous leukocyte-depleting medium interposed between the first container (bag 12 in Figure 1 of D1) and the second container (bag 14 in Figure 1 of D1). Correspondingly, D1 does also not disclose passing the supernatant layer of the separated biological fluid, i.e. the supernatant PRP obtained by centrifugation of whole blood and expressed into said bag 14, or any further blood product separated therefrom, through a further leukocyte-depleting medium, as required by claim 21 of the patent in suit.

5. *Technical problem*

5.1 Starting from the system disclosed in D1, the technical problem to be solved can be seen in the provision of a system suitable for separating a biological fluid such as blood into two or more fractions of improved quality, in particular of reduced leukocyte content.

5.2 It is evident and it has not been disputed that the arrangement of a further leukocyte-depleting porous medium in the conduit leading from the first container to the second container permits obtaining subsequently further product fractions (such as PRP, plasma and/or PC in the case of whole blood separation) also depleted in undesirable leukocytes, and hence improved in quality in comparison to the ones obtainable with the system of D1. Thus, it is plausible that this technical problem has indeed been solved by a system according to claim 1, e.g. when used for processing whole blood separated by centrifugation. Moreover, in comparison to a system for blood separation as shown in D1, no additional bag is required.

6. Hence, it remains to be seen whether starting from the said closest prior art, and considering the prior art relied upon by the appellant, the provision of a system as claimed was an obvious solution of the stated technical problem.

7. D1 itself is not concerned with the leukocyte content of the PRP expressed from the primary bag 12 or of any blood products derived therefrom. Hence, taken alone, D1 cannot suggest the modifications required to arrive at a system according to claim 1 of the patent in suit.

8. Document D2 relates to the preparation of leukocyte-poor platelet suspensions by filtration of a leukocytes- and platelets-containing suspension through a fibrous filter medium.

8.1 The description of D2 repeatedly refers to the preparation of leukocyte-poor platelet **concentrates**

(emphasis added) to be used in particular for transfusions, see e.g. column 1, lines 8 to 12, column 2, lines 8 to 11, column 3, lines 36 to 38, column 4, lines 40 and 44, column 5, lines 55 to 57 and column 6, lines 11, 19 to 22 and 31. However, considering that D2 also refers more generally to the treatment of a "platelet suspension" (see e.g. column 1, 1st paragraph and claim 1), that it mentions suspensions of a "different liquid containing platelets, leucocytes and erythrocytes" (see column 6, lines 32 to 33) and that it refers to document D13 which undisputedly relates to the leukocyte filtration from both PCs and PRPs (see D2, column 3, last full paragraph and D13, page 2, lines 2 to 10 and examples 10 and 11), the board accepts that the disclosure of D2 is not restricted to the treatment of those concentrated suspensions of platelets which are usually designated as PCs in this particular technical field.

8.2 As pointed out by the appellant, D2 mentions that in D13 the best results in terms of leukocyte removal and platelet passage are reported in connection with the filtration of a PRP described in example 10. However, this statement concerns the specific previous prior art leukocyte-filtering materials and methods described in D13. Therefore the board does not accept that it represents an implicit suggestion to preferably carry out the method of D2 with PRP starting suspensions. The board observes that D2 mainly relates to the filtration of PCs for platelets transfusion (see e.g. column 5, lines 36 to 41 and 49 to 58; and column 6, lines 19 to 28). Anyway, the question of whether or not the filtration of a PRP as obtainable by centrifugation of

whole blood was indeed envisaged and disclosed by the authors of D2 may remain open, since even assuming this was the case, the board comes to the conclusion that a combination of the teachings of D1 and D2 does not, for the following reasons, lead to a system falling under the terms of claim 1 of the patent in suit (understood as indicated in point 3.2 above) in an obvious manner.

8.3 D2 is not concerned with and does not refer to those steps which necessarily precede the filtration of a platelet suspension, such as the whole blood collection, the separation of the blood into different fractions, or the transfer and collection of a platelet suspension. The system disclosed in D2 comprises a "**storage** reservoir for the starting suspension" (emphasis added), such as a plastic bag, a leukocyte depleting filter and a collecting reservoir for the leukocyte-poor suspension, which form a closed system, see claims 12 and 13, Figure 3 and column 4, line 42 to column 5, line 1. Other embodiments of closed systems are not described or suggested. Moreover, D2 is silent about the necessity of removing leukocytes from plasma fractions poor in platelets as may be obtained upon preparation of PCs.

8.4 As pointed out by the respondent at the oral proceedings, the teachings of D1 and D2 can be combined without having to modify a single feature of the systems disclosed in D1 and D2. A bag containing collected PRP or PC, as obtainable with a system according to D1, can be regarded as the starting platelet "storage reservoir" in the sense of D2. It can thus be used for storing the blood product and for subsequently using it as "reservoir for the starting

suspension" in a closed system according to D2, with the leukocyte-depleting medium being arranged downstream of the said reservoir. The separation of leukocytes, in accordance with the teaching of D2, from a platelet suspension such as PRP or PC contained in a bag and obtained according to D1 could thus be carried out by another operator, at some other location and at some later point in time. Hence, a straightforward combination of the teachings of D1 and D2 does not, without further considerations, lead to a system as shown in D1 (Figure 1) additionally comprising a leukocyte-depleting medium as disclosed in D2 arranged in the tubing connecting the primary blood collecting bag (12) with the satellite bag (14) of the system disclosed in D1, i.e. upstream of any bag foreseen for collecting PRP or PC.

9. Moreover, document D6, published after and expressly referring to D1, discloses a different approach to the aseptic separation of whole blood into several leukocyte-depleted products such as red cells, plasma and platelets by means of a closed multi-bag system.

9.1 According to D6, the whole blood collected from a donor is subjected to a leukocyte-removing filtration before its further separation into blood products suitable for transfusion. To this effect, the whole blood collected from the donor is passed through leukocyte-removing filter means into a "primary" bag. After removal of the blood colleting and filtering means, the filtered blood in the said primary bag may be subjected to centrifugation in order to obtain a supernatant PRP and an erythrocyte layer. The PRP may then be subjected to a further centrifugation to obtain plasma and PC in two

satellite bags. See in particular page 2, lines 6 to 10 and 17 to 18, page 8, lines 8 to 40, Figure 2, and claims 1, 2 and 8.

9.2 The introductory part of D6 contains an explicit reference to the system of D1, see page 2, line 40 to page 3, line 2. The latter is considered as disadvantageous not only because leukocytes are not removed from the plasma fraction, but also because it requires placing the leukocyte-depleting filter into the centrifuge together with the bag system (primary bag and satellite bags). This measure is stated to lead to a danger that the filter means and the bags may be destroyed due to the centrifugal force and the friction between bags and filter means during the centrifugation (page 2, line 52 to page 3, line 1.

9.3 Aware of the system of D1 and of the need to remove leukocytes from blood components for transfusions, the authors of D6 have thus deliberately turned away from a multi-bag closed system with a leukocyte-depleting filter arranged downstream of the bag receiving the whole blood to be centrifuged. Therefore, in the absence of any counter-arguments, D6 is considered to direct the skilled person away from further exploring any such systems, like the ones obtainable by integrating the closed system of D2 into the one of D1. The skilled person would thus not be encouraged to envisage the incorporation of a further leukocyte filter somewhere along tubing 18 of the system shown in D1 (Figure 1).

10. The appellant held that, considering the common general knowledge as illustrated by D11, the skilled person

would have been prompted to arrange the leukocyte filter disclosed in D2 in the tubing providing fluid communication between the primary bag 12 and one of the further bags 14 or 26 of the system disclosed in D1 (Figure 1).

10.1 D11 is a scientific publication concerning the "importance of white blood cells in platelet storage" (see its title). From the results of the experiments described, the authors conclude that white blood cells "significantly affect the metabolic activity of platelet concentrates and that the quality of stored platelets can be improved by reducing the number of contaminating leukocytes", and that "it seems likely that the quality of stored platelets can be enhanced by using techniques for platelet isolation that minimize the number of residual leukocytes", see the penultimate sentence of the abstract and page 107, last sentence.

10.1.1 According to the experiments described whole blood was collected and subjected to a first centrifugation in bags. The obtained PRP was expressed, and thereafter either i) subjected to a second centrifugation to obtain a PC; or ii) subjected to a slow centrifugation to separate leukocytes, followed by further centrifugation to separate a PC. Both types of PCs were stored for 72 hours, and samples were drawn daily. It was found that the pH after 72 hours of storage of the leukocyte depleted PCs obtained according to method ii) was significantly higher than the pH after 72 hours of the leukocyte-containing PCs obtained according to method i), see e.g. page 102, section "Methods", page 106, section "Discussion", second paragraph.

10.1.2 It can thus be gathered from D11 that the storage of PCs which are not leukocyte-depleted for 3 days or more leads to a drop in their quality. However, D11 does not address or suggest the use of porous media for leukocyte depletion. Moreover, although samples have been drawn daily, D11 does not report any data for leukocyte-containing PCs stored for periods of less than 3 days. Hence, no conclusion can be drawn from D11 concerning possible advantages of a separation of the leukocytes from the platelets within a substantially shorter period of e.g. several hours.

10.1.3 On the other hand, as pointed out by the respondent during the oral proceedings, the separation of freshly donated blood into several fractions such as red cells and PC, and their leukocyte depletion, can easily be carried out within several hours using the devices known from D1 and D2. More precisely, the system of D1 could be used for obtaining a bag containing leukocyte-depleted PRC, and a bag of PC still containing leukocytes. The said PC-containing bag could then be separated from the system of D1 and then be subjected to the method described in D2 for removing leukocytes from the PC. This was not disputed by the appellant. PCs obtained in this manner would thus not suffer from a significant quality drop upon storage. Hence, the mere need for a relatively rapid processing of the donated blood does not require making constructional changes to the systems known from D1 and D2.

10.2 Consequently, even assuming for the sake of argument that the findings of D11 indeed belonged to the common general knowledge of the skilled person, this knowledge would not, without applying ex post facto

considerations, further prompt the skilled person seeking to obtain a high quality PC to modify the specific system of D1 (Figure 1) in a particular manner. More particularly, it would not give the skilled person an incentive to combine the teachings of D1 and D2 by arranging a leukocyte-depleting medium as disclosed in D2 in the tubing connecting the primary blood collecting bag (12) with the satellite bag (14) of the system disclosed in D1. The other modification considered to be obvious by the appellant, i.e. the arrangement of the porous medium between a PC-containing bag and a further satellite bag of the system of D1, would not lead to a system falling under claim 1 understood as indicated in point 3.2 above, since the filter would necessarily have to be arranged downstream of the bag 14, and hence not upstream of the second container in the sense of claim 1.

11. Summarising, the arguments presented by the appellant are not sufficient to establish that a skilled person confronted with the stated technical problem, even when bearing in mind and taking into consideration the teaching of D11, would, in the absence of ex post facto considerations, combine the teachings of D1 and D2 in a manner leading to a system covered by the first alternative of claim 1 of the contested patent, i.e. to a system wherein a porous leukocyte depleting medium as described in D2 is incorporated into the system of D1 in the fluid communication path (tubing 18) through which the supernatant PRP is expressed from the "primary" container (bag 12) and transferred into the next container (bag 14).

12. The same conclusion must apply to the second alternative covered by claim 1, which differs from the first alternative in that it additionally requires that the porous medium interposed between the first container and the second container is a combined leukocyte depletion and red cell barrier medium. Document D3 relates to the leukocyte depletion from platelet concentrates (see e.g. claims 1 and 47) and is thus not more relevant than D2 and D11 concerning the position of a further porous medium.

13. As indicated in the contested decision and accepted by the appellant in its statement of grounds of appeal, claim 21 is directed to a method corresponding to the product features of claim 1. The appellant has repeatedly argued that claims 1 and 21 were very broadly worded and not limited to systems and methods involving centrifugation and/or the processing of whole blood. However, in support of its objection as to lack of inventive step, it did not present further lines of argument based on prior art documents other than D1, D2 and D11. In the absence of such arguments, the board has no reason to take another position to that of the opposition division as far as claim 21 is concerned. For reasons analogous to those given here above in connection with the system of claim 1, the appellant's arguments do not convince the board that the method of claim 21 is obvious in view of D1, D2 and D11.

14. The other documents cited by the appellant contain no additional information which, in combination with the preceding documents, would point towards the system of claim 1 and the corresponding separation method of claim 21 of the contested patent.

15. The system and the method covered by claims 31 and 51 of the patent in suit rely on the use of a "red cell barrier medium" between the first container (11) and the second container (41) in addition to the use of the porous leukocyte-depleting medium interposed between the first container and the third container. In the contested decision, it was held that since a red cell barrier in the sense of the invention was not disclosed in any of the documents cited by the opponent, the subject-matter of claims 31 to 60 was novel and inventive.

15.1 In its statement of grounds of appeal, the appellant did not expressly contest this reasoning. It nevertheless attacked claims 31 and 51 on the ground of lack of inventive step "for the same reasons" as claims 1 to 30, because of their "analogy" with the latter. It also alleged that D3 disclosed a leukocyte-depleting medium which was also suitable for removing red blood cells, although only in connection with its objection raised against the second alternative covered by claims 1 and 21.

15.2 However, the passage of D3 cited by the appellant (see column 14, lines 40 to 45) does not appear to relate to a red cell barrier within the meaning of the contested patent (see section [0063], second sentence). Moreover, as already mentioned above, D3 is concerned with the depletion of leukocytes from platelet concentrates. The appellant has provided no argumentation as to why the skilled person would consider this document at all, let alone why and how it would consider combining some part of its teaching with the closest prior art D1.

15.3 The newly cited documents D11 to D13 also do not refer to a red cell barrier in the sense of the patent in suit. Under these circumstances, and in the absence of further supporting arguments of the appellant, the board has no reason to question the positive finding of the opposition division concerning the presence of an inventive step underlying claims 31 to 60, which relate to systems and methods relying on the use of such a red cell barrier.

16. The conclusions reached for independent claims 1, 21, 31 and 51 also apply claims 2 to 20, 22 to 30, 32 to 50 and 52 to 60 since they depend on the former.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Wallrodt M. Eberhard