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D E C I S I O N
of 6 June 2002

Case Number: T 0708/98 - 3.3.5

Application Number: 91912037.8

Publication Number: 0484517

IPC: B01D 35/01

Language of the proceedings: EN

Title of invention:
Venting System

Patentee:
PALL CORPORATION

Opponent:
Fresenius Medical Care Deutschland GmbH
Terumo Kabushiki Kaisha Head Office
HemaSure, Inc.

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (no): obvious modification of the closest prior art"

Decisions cited:
-

Catchword:
-

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Case Number: T 0708/98 - 3.3.5

D E C I S I O N
of the Technical Board of Appeal 3.3.5
of 6 June 2002

Appellant: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 28 May 1998 revoking European patent No. 0 484 517 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: R. K. Spangenberg
Members: A.-T. Liu
J. H. van Moer

Summary of Facts and Submissions

I. European patent No. 0 484 517 was granted with a set of claims consisting of an independent claim 1 for an assembly, with claims 2 to 4 depending thereon, an independent method claim 5, with claims 6 to 7 depending thereon, and claim 8 depending on any of the preceding assembly or method claims. The independent claims read as follows:

"1. A blood or blood component processing assembly comprising:
A functional biomedical device (14,24) for treating blood or blood components including a leukocyte depletion filter;
a conduit (12,22) connected to the functional biomedical device, and
a first gas inlet (13,23) upstream of the functional biomedical device, said gas inlet in communication with the functional biomedical device and the conduit, said gas inlet including a liquophobic membrane for passing gas therethrough and having a bacterial blocking pore rating.

5. A method of processing blood or blood components comprising:
passing blood or blood components through a conduit (12,22) and a leukocyte depletion filter of a functional biomedical device (14,24) for treating blood or blood components connected to the conduit; and flowing gas through a first gas inlet (13,23) upstream of the functional biomedical device, said first gas inlet in communication with the functional biomedical device and the conduit, to recover blood or blood

components in the functional biomedical device and/or the conduit, said first gas inlet including a liquophobic membrane for passing gas therethrough and having a bacterial blocking pore rating."

II. Three notices of opposition were filed against the patent, supported, inter alia, by the following documents:

D5: JP-A-2 063 470 (with English translation)

D6: US-A-4 009 714

D7: JP-A-64 005 563 (with English translation)

D8: US-A-4 126 558

Reference to D5 and D7 will be made in this decision to the English translation of these documents.

The patentee relied inter alia on the following documents:

P2: Report by Jerard Seghatschian, Ph.D., dated 28 August 1997.

III. At the end of the oral proceedings which took place before the opposition division, the patent was revoked on the ground that the subject-matter of the independent claims 1 and 5 lacked an inventive step.

IV. An appeal was lodged by the patentee who, with the statement of the grounds of appeal, filed a first and a second auxiliary set of claims.

V. Claim 1 of the first auxiliary request was essentially as granted, except that the introductory part read:

"A blood or blood component processing assembly for use in closed systems comprising ...".

Likewise, claim 5 of the first auxiliary request was as granted except for the introductory part which read:

"A method for processing blood or blood components using a closed system comprising ...".

Claim 1 of the second auxiliary request was further amended with respect to claim 1 of the first auxiliary request in that it incorporated at the end of the claim the additional phrasing "and a gas outlet downstream of the functional biomedical device, said gas outlet including a membrane for passing gas therethrough and having a bacterial blocking pore rating."

Claim 5 of the second auxiliary request was amended with respect to claim 1 of the first auxiliary request to include, prior to the step of flowing gas through a first gas inlet, the additional feature of "flowing gas ahead of the blood and blood components through a gas outlet downstream of the functional biomedical device, said gas outlet including a membrane for passing gas therethrough and having a bacterial blocking pore rating."

The dependent claims 2 to 4 and 6 to 8 of both auxiliary requests were as granted.

VI. At the oral proceedings, which took place on 6 June 2002 in the absence of respondent Hemasure Inc., the appellant submitted a third auxiliary request based on the method claims 5 to 8 of the first auxiliary request.

VII. The appellant's arguments, submitted orally and in writing, may be summarised as follows:

- With regard to the closest prior art D5, the problem to be solved by the patent in suit was to provide an improved assembly for processing blood and blood products in closed systems.

- The solution as proposed in claim 1 was an assembly characterised by a gas inlet upstream of the functional biomedical device. In D5, the gas inlet was downstream of the leukocyte filter.

To demonstrate the advantage of the claimed assembly, the appellant produced at the oral proceedings a sample featuring a gas inlet upstream of the functional biomedical device.

VIII. The respondents' arguments were briefly as follows:

- The assemblies as claimed were not restricted to the embodiment used for demonstration at the oral proceedings. An inventive step could therefore not be based on an advantage which may be exhibited by the sample but was not related to technical features stipulated in the claims.

- With regard to D5, the problem to be solved by the patent in suit could only be seen in the provision

of a further assembly for processing blood components.

- Assemblies in which a gas inlet was arranged upstream of the functional biomedical device were numerous in the art.

- D5 not only disclosed an assembly suitable for use in closed systems but a closed system per se.

- The assembly according to D5 was also provided with a gas outlet.

- The claimed assemblies and methods therefore lacked an inventive step.

IX. The appellant requested that the decision under appeal be set aside and, as main request, that the patent be maintained as granted or, in the alternative, on the basis of the first or second auxiliary request filed with letter of 2 October 1998 or on the basis of claims 5 to 8 of said first auxiliary request (third auxiliary request).

The respondents Terumo Kabushiki Kaisha and Fresenius Medical Care Deutschland GmbH requested that the appeal be dismissed.

Reasons for the Decision

1. *Main request*

1.1 Claim 1 is directed to a blood or blood component processing assembly essentially defined by the

following features:

(i) a biomedical device including a leukocyte filter,

(ii) a conduit connected to the biomedical device,

(iii) a gas inlet upstream of the biomedical device, in communication with the conduit and said device,

(iv) the gas inlet including a liquophobic membrane for passing gas therethrough and having a bacterial blocking pore rating.

1.2 The Board concurs with the parties in that D5, which discloses an assembly comprising the above features (i), (ii) and (iv), should be considered to represent the closest prior art. The known assembly further incorporates at least one gas communicating part which assumes both functions of a gas inlet and outlet. The description, however, only indicates that this gas communicating part is located on the housing of the biomedical device but not as to whether it is upstream or downstream of the biomedical device (see claims 1 to 4, description page 12, first full paragraph, to page 14, first full paragraph).

A cross section of the filtering device according to D5 is best seen in Figure 6 showing a housing 1 provided with an inlet 2 and an outlet 3, which are connected to an inlet plenum A and outlet plenum B, respectively. The inlet and outlet plena are separated by a filtering material 12. The gas inlet 6 with its seal 7' and membrane 15 is on the outer side of the housing 1 and

in direct contact with the outlet plenum B. According to the description, at the end of the filtering process, some of "the filtered erythrocyte preparation remains in the filtrate flowing spaces B and in the conduit" leading to the blood recovery bag. "Therefore, when the seal 7' is peeled off for introduction of air therefrom, the erythrocyte preparation flows downward by gravity head to be collected in the blood recovery bag" (page 14, first full paragraph). The Board thus deduces from the description and Figure 6 that the gas inlet is in direct contact with the filtrate side of the filtering device 1. The Board therefore concurs with the appellant that the **gas communicating part** is in D5 downstream of the leukocyte filter, and consequently **downstream of the biomedical device**.

1.3 With reference to the sample demonstrated at the oral proceedings, the appellant has submitted that in view of D5, the technical problem to be solved by the patent in suit is the provision of an assembly

(a) for treating blood in "closed systems",

(b) which gives an improved yield of filtered blood,

(c) with extended shelf life of the blood product and

(d) which requires less personnel for its handling.

1.4 It is irrefutable that the solution proposed in **claim 1** is an assembly which is only distinguished from that of D5 in that the **gas inlet is located upstream of the biomedical device**.

1.5 The question that needs be addressed by the Board is

therefore not as to whether the assembly provided for demonstration at the oral proceedings solves the technical problem(s) as stated in point 1.3 above but whether the sole distinguishing feature of the proposed solution, namely the different location of the gas inlet, is essential for solving said problem(s).

1.5.1 Re. partial problem (a)
Use in a closed system

The appellant has conceded that claim 1 is not directed to a closed system but that the claimed assembly is arranged such that it can be used in a closed system. In the Board's view, however, the assembly according to D5 is equally suitable for use in a closed system (for details, reference is made to point 4.2 below). The Board therefore holds that the partial problem in question does not exist with respect to D5.

1.5.2 Re. partial problem (b)
Filtration yield

The respondents have observed that D5 expressly states that "almost all of the blood or other liquid remaining in the housing after the treatment can be discharged from the housing by opening the on-off means and introducing the air, resulting in tremendously reduced amount of the blood remaining in the housing. Effective use of approximately 100% of the precious blood or other liquid is thereby enabled" (page 15, first full paragraph). In consequence, the yield is already maximised in D5.

The appellant has submitted that the above statement in D5 has to be seen in the light of the fact that the gas

inlet in D5 is downstream of the blood filter. Upon opening of that gas inlet, air will not get through the wet filter, due to its surface tension, so that only the plenum B on the outlet side of the filter will be drained. Thus, there will be blood remaining in the inlet plenum A upstream of the filter and in the conduit connecting the blood bag with the filtering device (see also D5, Figure 6 and point 1.2 above). Thus, the above quoted passage in D5 should only be interpreted as relating to an assembly which allows "100% recovery of the filtered blood". The appellant, however, concedes that due to the same occurrence of surface tension, a portion of the blood will remain in the claimed assembly at the end of the blood processing process despite the gas inlet being fully open (see also patent in suit, column 15, lines 40 to 44 and letter dated October 18, 2002, page 4, last paragraph to page 5, paragraph 1 and page 7, paragraph 3). The difference with respect to D5 is that, since the gas inlet is on the upstream side of the filter, the remaining blood will be in the outlet plenum of the housing and in the conduit leading to blood recovery bag. The advantage here is that sections of the blood filtrate remaining in the conduit downstream of the filter could be put to useful purpose and therefore should be accounted as part of the recovered product.

Even if the effect of the surface tension is contested by the respondents (see point 1.5.5 below), the Board can interpret in favour of the appellant that, at best, neither assembly allows full use of the blood to be filtered. In D5, part of starting material will remain upstream of the filter whilst with the claimed assembly, part of the filtrate will not reach the recovery bag. Since the volumes made up by the conduits

and the plena, upstream and downstream of the filter, are neither stipulated in the claim nor indicated in the prior art, the Board cannot see how a comparison can be drawn as to the volumes of blood or blood components held up in those parts after the filtration has been completed. This consideration is not altered by the (unproven) hypothesis that, with the claimed assembly, the filtrate remaining in some sections of the downstream conduit could be recovered as part of the yield. Consequently, the Board is not convinced that the claimed assembly achieves the aim of improving the blood filtration yield with respect to D5.

1.5.3 Re. partial problem (c)
Shelf life of blood product

It is well known in the art that air present in stored blood or blood components may decrease their storage life. However, there is no indication in the patent in suit, nor has the appellant submitted, that the gas inlet in any way contributes to alleviating this problem. On the contrary, it is clearly suggested in the description that the assembly be provided with a gas outlet so that gas can be removed during the initial collection and processing steps (column 2, lines 11 to 33; column 3, lines 3 to 7; column 4, lines 17 to 21 and column 8, lines 29 to 35).

The same problem arising from the presence of air in blood products is addressed in D5 which offers the same solution, namely the provision of a gas outlet to remove air (page 3, first full paragraph and page 14, last paragraph). The Board therefore cannot accept that the patent in suit solves the technical problem of extending the shelf life of the filtered blood in

respect of D5.

1.5.4 Re. partial problem (d)
Ease of handling

The appellant has explained that, using the claimed assembly, the gas inlet may be opened at the beginning of the filtration process to displace the blood or blood components on the upstream side of the filter. Due to surface tension of the wetted filter, the liquid flow would automatically stop when air contacts the face of that filter. Thus, no control by personnel would be required up to the completion of the filtration process. On the other hand, a gas inlet located downstream of the filter as in D5 can only be opened at the end of the filtration process and personnel is thereby required to shut it off in time so that air may not be introduced into the blood recovery bag with the filtrate.

The respondents have replied that the pore size of a leukocyte depletion filter is known to vary over a wide range so that claim 1 encompasses those filters which are still capable of passing air at low pressures even when they are wet. Furthermore, the recommendation in the patent in suit to separate purge air from the blood product would imply that air introduced for draining the assembly must have passed through the wet filter (see column 17, lines 21 to 36, in particular lines 33 to 34). The occurrence of surface tension invoked by the appellant is therefore strongly contested.

Leaving the question pertaining to the surface tension at the wetted filter open, the Board observes that personnel is required to the same extent for opening

the gas inlet, whether it be upstream or downstream of the filter. Furthermore, as soon as the gas inlet is opened in D5, the blood remaining in the downstream part of the filter will be drained instantly so that additional time is barely required for the same person to turn it off. Therefore, the Board in any case fails to recognise that significant saving in personnel can be achieved with the present assembly.

1.5.5 As corollary of the above, the Board holds that, with respect to D5, the technical problem solved by the patent in suit can only be seen in the provision of a further assembly for processing blood or blood components having substantially the same advantages as those disclosed in the prior art.

1.6 The question is therefore whether the alternative of providing that gas inlet upstream of the functional biomedical device as stipulated in claim 1 rather than downstream of such device as in D5 is obvious in view of the available prior art.

It is undisputed that numerous assemblies exist in the prior art in which a gas inlet is incorporated upstream of a functional biomedical device. For example, D6 discloses an intravenous solution filter unit (thus, a functional biomedical device) in which the filter unit 30 is connected to an upstream conduit 39 which includes a liquid impermeable filter 40 (see title, Figure 6 and column 5, lines 16 to 18). D7 discloses an apparatus for removing impurities in blood which incorporates a three-way cock 20 upstream of the filters 6 and 7 (see Figure 1, description page 4 second paragraph and legends, page 6). In D8, the blood filtration unit comprises a filter cartridge disposed

within a filter housing. Attached to the filter housing is a drip chamber and disposed in the side wall of the drip chamber is an air valve 17 (column 1, lines 62 to 66, column 3, lines 15 to 16, Figure 2).

In D6, the air is introduced through the filter media 40 into the container to equalise the pressure within the container and provide a continuous flow of solution (column 5, lines 17 to 21). In D7, the three-way cock is opened to introduce air and to push out the plasma remaining in the filter (page 4, first sentence of paragraph 2). In D8, the valve is also opened to drain the filter unit (D8, column 2, lines 28 to 30).

In summary, the available prior art not only provides examples of assemblies exhibiting a gas inlet upstream of a functional biomedical device, these gas inlets also serve the same purpose as in the patent in suit and in D5, namely to equalise the pressure in the system so that liquid can be drained from the system (see D5, page 14, first full paragraph and patent in suit, column 17, lines 45 to 59). The Board therefore holds that, when seeking an alternative to the assembly according to D5, the skilled person would most naturally emulate examples in the art which perform the same function. In doing this he would provide a gas inlet upstream instead of downstream of the functional biomedical device. The modification as proposed in claim 1 therefore lacks an inventive step with regard to D5 in combination with either of D6 to D8 (Article 56 EPC).

2. *First auxiliary request*

The text of claim 1 of the present request differs from

that of claim 1 of the main request in that it now expressly incorporates an intended use ("assembly for use in closed systems"). The Board construes such stipulation as an additional functional feature requiring that the claimed assembly be suitable for said use.

As is already indicated in point 1.5.1 above and further expounded in point 4.2 below, the Board is convinced that the assembly disclosed in D5 is also suitable for use in closed systems. The finding of lack of inventive step for claim 1 of the main request is therefore also valid for present claim 1.

3. *Second auxiliary request*

3.1 Claim 1 of the present request further stipulates the incorporation of a gas outlet downstream of the biomedical device.

3.2 The appellant has not submitted that the problem to be solved with the additional feature is other than to remove air during the initial and processing steps (see also point 1.5.3 above).

3.3 It is irrefutable that the proposed solution is not new per se, as is also already noted in point 1.5.3 above. It is still the case that the assembly proposed in claim 1 is modified with respect to D5 only in that one of the gas communicating parts is moved upstream of the filter to serve as gas inlet.

3.4 In the Board's judgment, the change of location of the gas inlet is obvious for the same reasons as indicated in point 1.6 above. On the other hand, the appellant

has not indicated that the separated gas inlet upstream and gas outlet downstream of the filter would interact in a special way. As a consequence, the finding regarding claim 1 of the main and first auxiliary requests applies mutatis mutandis to present claim 1.

4. *Third auxiliary request*

4.1 The only independent claim of the present request essentially stipulates that :

(i) a closed system is used for processing blood or blood components;

(ii) blood or blood components are passed through a conduit and a leukocyte depletion filter; and

(iii) gas is passed through an inlet upstream of the filter to recover blood or blood components in the functional biomedical device and/or the conduit,

(iv) said gas inlet includes a liquophobic membrane for passing gas therethrough and has a bacterial blocking pore rating.

4.2 Since claim 1 expressly stipulates the **use of a closed system**, the Board needs to clarify the meaning of the expression "closed system" before an assessment on inventive step can be made.

4.2.1 The appellant has made reference to the report P2 in which the author declares that

"the term "closed system" as understood in the art of

blood processing refers to a system that allows processing of blood or blood components without compromising the sterility of the system. The elements of the closed systems are manufactured by methods which guarantee that the bacterial sterility of the system contents is maintained. Closed systems are produced as a fully assembled product under sterile manufacturing conditions. Alternately, closed systems can be provided just prior to use by means of special "sterile docking" techniques".

An indication for an open system is that the processed blood components must be used within 24 hours, otherwise they must be discarded due to fear of contamination by bacterial growth (see item 9, pages 3 to 4).

In compliance with that report, the appellant has submitted that the term "closed system" essentially means a "sterile system" that allows processing of blood or blood components without compromising its sterility. A proof that the system according to the patent in suit is closed/sterile arises from the requirement of a bacterial blocking membrane for the gas inlet. In contrast, the system according to D5 would not be considered a closed system since there is no indication for example that the connection between the conduit 24 and the blood bag 20 as illustrated in Figure 7 of D5 is a "sterile docking", or that the connection between the conduit and leukocyte filter 1 is made under sterile conditions. Also, the extended portion of the conduit would not be an embodiment usually applied in closed systems.

4.2.2 The above assertions are contested by the respondents

who pointed out that such interpretation is neither supported by the patent in suit nor consistent with the disclosure of D5.

4.2.3 Indeed, the Board notes that the patent in suit contains neither a direct indication nor a reference to another document as to the exact meaning given to the term "closed system". A concrete embodiment of a closed, sterile blood processing system according to the patent in suit is, however, illustrated in Figure 1. The assembly is shown to include a first container 11 for collecting or holding blood, a second container 17 for receiving processed blood, conduits 12 and 15 for interconnecting the first and second container. Interposed between the containers is a functional biomedical device 14. This embodiment includes a gas inlet 13 in conduit 12 upstream of the device 14 and a gas outlet downstream of that device (see also description at column 14, lines 26 to 39). In the Board's judgment, irrespective of the question as to whether in the present case the term "closed" and "sterile" may indeed be used interchangeably, the criteria outlined by the appellant cannot be construed to imply technical features beyond those shown in this particular embodiment. In particular, the Board cannot accept the argument that a closed system must involve "sterile docking" since this is only cited in the report as one example for providing a closed system (see P2, page 3, penultimate paragraph: "closed systems **can** (emphasis added) be provided just prior to use by means of special "sterile docking" techniques").

The assembly disclosed in D5 essentially comprises the same items as illustrated in Figure 1 of the patent in suit, with the exception that the gas communicating

parts serving both as gas outlet and inlet are located downstream of the filter (see Figure 7, page 12, last paragraph to page 14, first paragraph, and page 16, first paragraph). In addition, the gas communicating part is provided with a filter that permits gas permeation but not the permeation of bacteria (page 2, claim 5). According to the appellant's own submission, such a bacterial blocking membrane only makes sense if the system is sterile and closed from the beginning. From the statement in D5 that the incorporation of a bacteria blocking membrane prevents a contamination of blood or blood products with bacteria and enables aseptic recovery of the liquid (page 16, paragraph 1), the Board further deduces that the known system also allows processing of blood or blood components without compromising the sterility of the system. Lastly, the assembly is applied to the preparation of large amounts of blood products at a blood centre and not only for bedside use (page 4, paragraph 1). There is no mention that the prepared blood products must be used within 24 hours for fear of subsequent contamination by bacteria during storage. Since the assembly of D5 fulfills the above criteria for a closed and sterile liquid treating device, it is a closed system within the meaning of the patent in suit.

4.3 It is undisputed that D5 discloses a method for processing blood or blood components using a leukocyte depletion filter. As discussed earlier, gas is passed through an inlet to recover blood or blood components, which gas inlet includes a liquophobic membrane for passing gas therethrough and has a bacterial blocking pore rating. The present process as claimed is thus distinguished from the process of D5 only in that gas is introduced upstream instead of downstream of the

filter (see point 1.2 above). As a consequence, the reasoning regarding claim 1 of the main and first auxiliary requests applies mutatis mutandis to the present method claim which is therefore found to lack an inventive step (see point 1.6 above).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

P. Martorana R. Spangenberg