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Datasheet for the decision of 30 March 2017

Case Number: T 1760/12 - 3.2.02

Application Number: 00904283.9

Publication Number: 1061971

IPC: A61M1/36

Language of the proceedings: EN

Title of invention:
Apparatus for dialysis with blood-warmer

Patent Proprietors:
Gambro Renal Products, Inc.
Gambro Industries SAS

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 123(2), 123(3), 84, 56
EPC R. 42
RPBA Art. 13(1), 13(3)

Keyword:

Late-filed auxiliary request - admitted (yes)
Amendments - extension beyond the content of the application as filed (no) - extension of protection of the patent (no)
Claim - clarity (yes)
Inventive step - (yes)

Decisions cited:

Catchword:

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Case Number: T 1760/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 30 March 2017

Appellant: (Patent Proprietor 1)	Gambro Renal Products, Inc. 10810 West Collins Avenue Lakewood, CO 80215 (US)
(Patent Proprietor 2)	Gambro Industries SAS 7, Avenue Lionel Terray 69330 Meyzieu (FR)
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Appellant: (Opponent)	Fresenius Medical Care Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg v. d. H. (DE)
Representative:	Herrmann, Uwe Lorenz Seidler Gossel Rechtsanwälte Patentanwälte Partnerschaft mbB Widenmayerstraße 23 80538 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 8 June 2012 concerning the maintenance of European patent No. 1061971 in amended form.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	D. Ceccarelli
	M. Stern

Summary of Facts and Submissions

I. The opponent and the patent proprietors have appealed the Opposition Division's decision, dispatched on 8 June 2012, that European patent No. 1 061 971 could be maintained as amended according to then pending auxiliary request 9.

II. The notice of appeal of the appellant opponent (hereinafter the "opponent") was received on 31 July 2012. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 18 October 2012.

III. The notice of appeal of the appellant proprietors (hereinafter the "proprietors") was received on 8 August 2012. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 17 October 2012.

IV. The proprietors replied to the opponent's statement of grounds with letter dated 4 March 2013. The opponent replied to the proprietors' statement of grounds with letter dated 4 March 2013. Both parties filed further written submissions after their replies to the other party's statement of grounds.

In particular, with letter dated 8 November 2013, the opponent filed the following documents:

D37: "Renal replacement therapy after repair of congenital heart disease in children", Fiona Fleming et al., The Journal of Thoracic and Cardiovascular Surgery, Volume 109, Number 2, pages 322 to 331, February 1995;

D38: "Evaluation of a New Fluid Warmer Effective at Low to Moderate Flow Rates", Robert G. Presson et al., Anesthesiology, Volume 78, Number 5, pages 974 to 980, May 1993.

V. The Board summoned the parties to oral proceedings and set out its provisional opinion in a communication dated 23 December 2016.

VI. Both parties filed further written submissions in preparation for the oral proceedings.

VII. Oral proceedings took place on 30 March 2017.

The proprietors requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of auxiliary requests I and II, both filed with letter dated 28 February 2017.

The main request filed with the same letter was withdrawn.

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

VIII. The following document is also mentioned in the present decision:

D1: EP-A-0 754 468.

IX. The only claim of auxiliary request I reads as follows:

"A continuous renal replacement therapy system comprising:

a continuous renal replacement therapy monitor (15) having a venous pressure transducer (80), a detector for protecting against air embolism (90); and a venous line clamp (95); and

a blood warmer (20) attached to the continuous renal replacement therapy monitor (15); and

a disposable tubing set (35) adapted for engagement with the continuous renal replacement therapy monitor (15), and comprising a dialyser (40); and a blood tube segment (100) engaged with the blood warmer (20) so that the blood warmer (20) is arranged to transfer heat to blood flowing in the blood tube segment (100), the blood tube segment (100) being located in flow communication with and downstream of the dialyser (40) and upstream of the venous pressure transducer (80), the detector (90) and the venous line clamp (95) of the continuous renal replacement therapy monitor (15), the disposable tubing set (35) further comprising:

a first venous line (45);

a second venous line (60);

a separable connector pair (50, 55) intermediate the first venous line (45) to the second venous line (60), the separable connector pair (50, 55) being separated;

a third venous line (70);

a sample access site (65) intermediate the second venous line (60) and the third venous line (70);

a fourth venous line (85); and

a venous pressure pod (75) intermediate the third (70) and fourth (85) venous line;

wherein said fourth venous line (85) is adapted to be received by, and cooperate with, the detector and the venous line clamp (95) for protecting against air embolism (90),

the blood tube segment (100) being an extension line (100) received by and cooperating with the blood warmer (20) and having a first end (105) and a second end (110), each end having one half of a connector pair interconnected with the halves of the separable connector pair (50, 55) of the disposable tubing set, whereby the extension line is intermediate the first (45) and second (60) venous lines."

X. The opponent's arguments may be summarised as follows:

Admissibility of auxiliary request I

Auxiliary request I had been filed by the proprietors only a little more than a month before the oral proceedings. This was well after the reply to the opponent's statement of grounds, at a very late stage of the appeal proceedings. The proprietors had had no reason to file it so late. They could and should have filed it much earlier. The claim of auxiliary request I had not yet been in the proceedings as an independent claim. The fact that the opponent had already commented on claim 2 of the patent as granted, which comprised some of the features of the claim of auxiliary

request I, was no reason to admit that request. Moreover, the proprietors had provided no arguments on novelty and inventive step of the subject-matter of the claim of auxiliary request I when they filed it. The claim and the proprietors' arguments presented for the first time during the oral proceedings raised new issues difficult to deal with by the opponent and the Board without adjournment of the oral proceedings. For these reasons auxiliary request I should not be admitted into the proceedings.

Article 123(2) EPC

The features "a disposable tubing set (35) adapted for engagement with the continuous renal replacement therapy monitor (15), and comprising a dialyser (40); and a blood tube segment (100) engaged with the blood warmer (20) so that the blood warmer (20) is arranged to transfer heat to blood flowing in the blood tube segment (100), the blood tube segment (100) being located in flow communication with and downstream of the dialyser (40) and upstream of the venous pressure transducer (80), the detector (90) and the venous line clamp (95) of the continuous renal replacement therapy monitor (15)" were an arbitrary selection of individual features from three "significant aspects" of the invention as presented on page 4, line 15 to page 5, line 2 of the application as originally filed. This amounted to a non-allowable intermediate generalisation. Moreover, the application as originally filed did not disclose any relationship between those "significant aspects" and the other claimed features that were already present in claim 1 of the patent as

granted. It followed that the combination now claimed was not disclosed in the application as originally filed.

Moreover, the blood tube segment was defined as being simply engaged with the blood warmer so that heat could be transferred, whereas according to the original disclosure on page 4, lines 15 to 18 the blood warmer was "designed to engage and hold" the blood tube segment "to transfer heat at a closely controlled temperature". No basis for the claimed generalisation could be found in the application as originally filed, especially in the light of the "object of the invention" as presented on page 4, lines 5 and 6, according to which the local temperature of the blood had to be limited to levels which were not expected to damage the blood.

The semicolon after the first mention of a dialyser in the claim implied that the blood tube segment defined afterwards was not a part of the disposable tubing set, but only of the continuous renal replacement system. The original application did not disclose such a configuration. Additionally, on page 4, line 15 to page 5, line 2 there was no disclosure either that the blood tube segment belonged to the disposable tubing set.

Further, a specific assembly state was claimed, according to which the blood tube segment was engaged with the blood warmer, and the detector for protecting against air embolism and the venous line clamp were mounted on the disposable tubing set. However, the position of the dialyser in the system was not defined. Also, the venous pressure transducer was not defined as being connected to

the venous pressure pod. Such a configuration, in which some elements of the system were connected to the disposable tubing set and others were not, could only be realised during a specific method of operation of the device, which was not disclosed in the application as originally filed. Moreover, an assembly state in which the blood tube segment was engaged with the blood warmer was only disclosed in the description of a specific embodiment, which disclosed a very specific blood warmer with a very specific engagement with the blood tube set. For this reason, the system claimed was a non-allowable intermediate generalisation. Also, according to the original disclosure on page 4, line 22 to page 5, line 2, the "disposable tubing set" could be selectively connected to a disposable blood tube segment for engagement with the blood warmer. This implied the possibility of having the disposable tubing set and the disposable blood tube segment connected or not connected to each other, as shown in figures 2 and 3, whereas the claimed blood tube segment connected to the disposable tubing set excluded that possibility.

A "separable connector pair (50, 55) intermediate the first venous line (45) to the second venous line (60)" was claimed. At the same time, halves 50 and 55 of the separable connector pair should be connected to the extension line. However, such a configuration was not disclosed in the application as originally filed.

Article 123(3) EPC

A system was claimed in which the separable connector pair of the disposable tubing set was

separated and the extension line was introduced between the first and the second venous lines. According to the claims as granted, however, the first and the second venous lines were connected and could be separated by disconnecting the separable connector pair. They could therefore be in two different configurations, connected to each other or to connectors of the extension line. The subject-matter now claimed covered embodiments in which the first configuration would not be obtained. Moreover, according to the subject-matter of the patent as granted the connection of the separable connector pair to the extension line was only possible, but not actually effected. Claiming a system status in which the separable connector pair was connected to the extension line constituted an "aliud" to the subject-matter of the claims of the patent as granted, which infringed Article 123(3) EPC.

Article 84 EPC

The relationship between the claimed disposable tubing set and the other components of the claimed system was not clear. While on the one hand the disposable tubing set was generally defined as being adapted for engagement with the continuous renal replacement therapy monitor, on the other hand some elements were specifically claimed to be connected to each other. Because of these contradictory definitions the assembly state of the system was unclear. Moreover, some elements of the disposable tubing set were defined with reference to elements of the continuous renal replacement therapy monitor without specifying any functional interaction between them. For example, the function

of the venous line clamp in relation to the disposable tubing set was not clearly defined. Also the feature of the extension line "received by and cooperating with the blood warmer" was unclear. In particular it was left open whether the blood warmer had to comprise an opening for receiving the extension line or whether it was sufficient, in order for this feature to be fulfilled, that the extension line could be brought into contact with a surface of the blood warmer or even receive the blood warmer in its interior.

Also, the terms "downstream" and "upstream" defined method features which, in the context of a claim directed to a system, rendered its subject-matter unclear.

The definition of the connector pair as separable and, at the same time, separated was contradictory.

The semicolon after the first mention of a dialyser in the claim implied that the blood tube segment defined afterwards was not a part of the disposable tubing set, but only of the continuous renal replacement system. This rendered the relationship between the blood tube segment and the disposable tubing set completely unclear.

Article 56 EPC

The subject-matter of the claim of auxiliary request I was not inventive starting from D37 as the closest prior art, in combination with D38 and D1.

D37 and D38 had been filed by the opponent with letted dated 8 November 2013, after the reply to the proprietor's statement of grounds. Admitting them was at the Board's discretion, under Article 13(1) RPBA. The Board should exercise its discretion by admitting the documents, since they had been filed at an early stage of the appeal, before the issue of the summons to oral proceedings, and were very relevant, clear and concise in their disclosure, so admitting them would also contribute to procedural economy.

More particularly, D37 clearly disclosed a continuous renal replacement therapy system comprising a blood warmer similar to the claimed system. The blood warmer was identified as the "Hotline" product of company "Level 1 Technologies Inc.". D38 concerned this specific blood warmer, disclosing many features not present in D37. It followed that both documents were very relevant in combination.

D37 did not disclose that the blood warmer of the continuous renal replacement therapy system received and co-operated with an extension line with connectors as defined in the claim of auxiliary request I. Moreover, it did not disclose the claimed arrangement of the first to fourth venous lines comprising, in particular, a sample access site "intermediate" the second and third venous lines.

An extension line as claimed was however obvious in the light of the problem of increasing the flexibility of use of the system and of D38, which disclosed a thicker tubing line for heating blood

("Heated Delivery Tubing" in figure 1), connected to other tubing lines of the system.

The claimed arrangement of the first to fourth venous lines and the sample access site was obvious in the light of D1. Since the problem addressed by this distinguishing feature was different from that solved by the claimed extension line, a combination of three prior-art documents was permissible.

More particularly, the claimed sample access site addressed the problem of providing a disposable tubing set through which blood samples could be taken. D1 showed a tubing set for blood handling procedures with various venous lines and a sample port (figure 1). It explicitly mentioned that sample sites could be added anywhere in the tubing set (column 9, lines 36 to 41). In view of the formulated problem it would be obvious to the skilled person to implement the tubing set of D1 in the system of D37.

The subject-matter of the claim of auxiliary request I would therefore be arrived at without any inventive activity.

Rule 42 EPC

The description was not in conformity with the claim of auxiliary request I. In paragraph [0016] it was stated that the invention was described with reference to figures 1 to 7, while in paragraph [0017] it was stated that a preferred embodiment was described with reference to figures 1 to 5. This was contradictory. Moreover, figures 6 and 7 did not relate to the claimed invention as they

solely concerned the mounting of a blood warmer on a continuous renal replacement therapy system.

XI. The proprietors' arguments may be summarised as follows:

Admissibility of auxiliary request I

Auxiliary request I had been filed one month before the oral proceedings, as a reaction to the preliminary opinion of the Board presented in the communication accompanying the summons and as a reaction to the opponent's objections under Article 123(2) EPC. It did not raise any unexpected issues, as its only claim was the combination of claims 1 and 2 of the request held allowable by the Opposition Division in the impugned decision. The opponent had already commented on claim 2 of that request in its statement of grounds of appeal. Hence, it could not be surprised by the subject-matter of auxiliary request I. Moreover, auxiliary requests I and II replaced a number of previously filed auxiliary requests, in an attempt to streamline the procedure. The Board should therefore admit auxiliary request I into the proceedings.

Article 123(2) EPC

The subject-matter of the claim of auxiliary request I was generally derived from claims 1 to 3 and description page 4, lines 15 to page 5, line 2 of the application as originally filed. The mentioned passage in the description generally referred to aspects of the invention. Hence the features defined in that passage could be combined

with the other features of the invention as defined in broadest terms in the claim.

The claim contained all the essential features for obtaining two different technical effects. The first technical effect related to the presence of the separable connector pair, which permitted the coupling to the blood warmer, and the second related to the claimed position of the warmer and the other elements in the blood circuit. Functional definitions did not disclose fresh information in connection with a specific assembly state, but simply explained the operation of the claimed system.

A basis for a general dialyser being part of the disposable tubing set was found on page 7, lines 1 to 3 of the application as filed.

For the skilled person the definition of the blood tube segment being "engaged with the blood warmer" had the same technical content as the passage of the description as originally filed, page 4, lines 15 to 18, in which it was stated that the blood warmer was "designed to engage and hold" the blood tube segment. The capability of heat transfer "at a closely controlled temperature" according to page 4, lines 15 to 18 of the description as originally filed was not essential, since claim 1 as filed generally referred to a blood warmer without any requirement of that specific heat transfer. The blood tube segment was part of the disposable tubing set. For the skilled person it was implicit that, according to the claim, the blood tube segment had to be disposable. The definitions of the blood tube segment being

"engaged" with the blood warmer and the disposable tubing set being "adapted for engagement" with the continuous renal replacement therapy monitor did not add any fresh subject-matter, since the application as filed provided an explicit disclosure that the elements concerned could be engaged and disengaged due to the disposable nature of the tubing set. There was therefore a basis for claiming that the elements were either "adapted to be engaged" or "engaged". Claim 3 as originally filed provided a basis for an extension line received between halves 50 and 55 of the separable connector pair as defined in the claim of auxiliary request I.

Article 123(3) EPC

The definition that "the separable connector pair (50, 55) [...was] separated" restricted the scope of protection of the claim to one of the two alternatives provided by the more general definition of a separable connector pair. Hence, it did not infringe Article 123(3) EPC.

Article 84 EPC

The skilled person understood that the claim of auxiliary request I was directed to a system defined by structural and functional features. Each element of the system as well as their sequence and functions were clearly defined. For example, the terms "upstream" and "downstream" defined that sequence with reference to the intended direction of flow, even in a system in which blood was not currently flowing. Similarly, defining the connector pair as "separable" left open the

possibility of having it in a connected or separated state, and the further reference to the connector pair being "separated" simply restricted the claimed subject-matter to one of the two states. There was no inherent contradiction or ambiguity in defining the engagement of different elements in different terms.

From the wording of the claim it was also clear that the blood tube segment was part of the disposable tubing set and that the venous line clamp worked on the fourth venous line. That was in accordance with the disclosure of the patent.

Article 56 EPC

While it was recognised that D37 was a relevant document that represented the closest prior art, and no objections to its admission into the proceedings were raised, late-filed document D38 did not relate to a continuous renal replacement therapy system, but to intravenous fluid infusion in general. It was therefore not relevant and should not be admitted into the proceedings. There was no link between D37 and D38 other than the same trademark identifying the two warmers. However, a single trademark could relate to completely different warmers. D38 as a whole rendered it unlikely that the warmer it disclosed could be used in a continuous renal replacement therapy system.

Amongst other things, D37 did not disclose that the blood warmer of the continuous renal replacement therapy system received and co-operated with an extension line having at each end one half of a connector pair interconnected with the halves of

the separable connector pair of the disposable tubing set, and it did not disclose the arrangement of the first to fourth venous lines comprising, in particular, a sample access site "intermediate" the second and third venous lines as defined in the claim of auxiliary request I.

The claimed interconnection between the extension line and the separable connector pair of the disposable tubing set implied that the extension line could be removed from the system. Hence the system was capable of working in two different configurations, with or without warming. D38 did not teach this feature, since the connectors of the tubing set between which the extension line was positioned were not disclosed as being connectable to one another.

The position of the sample access site, downstream the extension line and the warmer, made it possible to collect air and gases that might develop in the heating process of the blood in the access site, as explained on page 8, lines 22 to 24 of the application as originally filed. Therefore there was no need for an additional drip chamber or other means for degassing the blood. Thus unwanted heat loss was avoided.

D1 was directed to a completely different issue, namely the possibility of reusing blood lines. This involved the use of connectors with a special design, as explained in column 9, lines 42 to 44, making it possible to wash the blood lines after use (column 10, lines 29 to 38). Hence, there was no reason why the skilled person would combine the teaching of D1 with D37. Moreover, the reason why

in the blood circuit of D1 an access site was present was not explained in the document.

It followed that inventive step had to be acknowledged.

Rule 42 EPC

Paragraphs [0016] and [0017] of the description were not in contradiction with the claimed invention. Moreover, if they had been, then the same contradiction would also have been present with respect to the claims of the patent as granted. Hence no modification of the description was required following the amendments made to the claims.

Reasons for the Decision

1. The appeals are admissible.

2. The invention

The invention relates to a continuous renal replacement therapy system comprising a continuous renal replacement therapy monitor, a blood warmer and a disposable tubing set. Figure 3 of the patent, depicted below, illustrates a system in accordance with the claim of auxiliary request I.

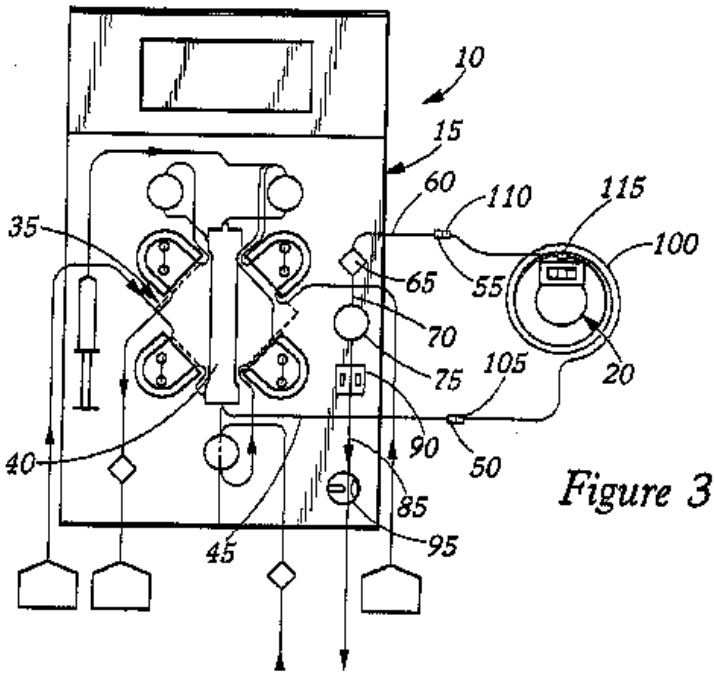

Figure 3

Continuous renal replacement therapy is a treatment for acute renal failure from which a patient may, in time, recover. It involves extracorporeal blood treatment which may include dialysis, ultrafiltration, hemofiltration, hemodiafiltration and similar processes (column 1, lines 11 to 14 of the patent).

Compared to the treatment of chronic (or permanent) kidney failure, which typically involves periodic dialysis treatments at relatively high blood flow rates for around three or four hours, continuous renal replacement therapy involves lower flow rates and is performed continuously, typically under the control of a continuous renal replacement monitor (15). This results in a treatment which is more easily tolerated by the patient's body and is therefore better suited for patients who have other underlying diseases or injuries or who are very young (column 1, lines 24 to 32). According to the claim of auxiliary request I the monitor (15) comprises a venous pressure transducer, a detector for protecting against air

embolism (90) and a venous line clamp (95).

In a dialysis treatment the blood circulating in the extracorporeal circuit experiences a loss of heat, which has to be compensated for by the patient's own metabolism. As explained in the patent (column 1, line 56 to column 2, line 2), continuous renal replacement therapy increases the heat loss potential of the blood, with the result that the patient, under certain circumstances, may experience a dangerous lowering of body temperature. The invention as defined in the claim of auxiliary request I comprises a blood warmer (20) as part of the continuous renal replacement therapy system in order to compensate for the heat loss (column 2, lines 3 to 20).

The claimed invention also includes a disposable tubing set (35) comprising, in particular, an extension line (100) received by and co-operating with the blood warmer (20) and having at each of its ends (105 and 110) one half of a connector pair interconnected with respective halves of a separable connector pair (50, 55) intermediate a first venous line (45) and a second venous line (60) of the tubing set. Moreover, a sample access site is intermediate the second venous line (60) and a third venous line (70), downstream of the blood warmer (20).

3. Admissibility of auxiliary request I

Auxiliary request I was filed by the proprietors after their reply to the opponent's statement of grounds and after oral proceedings had been arranged. This constitutes an amendment to the proprietors' case, the admission of which is at the Board's discretion under

Article 13(1) and (3) RPBA.

According to Article 13(1) RPBA "the discretion shall be exercised in view of inter alia the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy". Moreover, under Article 13(3) RPBA, amendments "sought to be made after oral proceedings have been arranged shall not be admitted if they raise issues which the Board or the other party [...] cannot reasonably be expected to deal with without adjournment of the oral proceedings". Another important criterion for assessing the admissibility of amendments to a party's case, according to the established jurisprudence of the boards of appeal, is their prima-facie relevance.

While the Board agrees with the opponent that the proprietors could have filed auxiliary request I before, it notes that the only claim of that request is the mere combination of claim 1 and its sole dependent claim 2 of the request held allowable by the Opposition Division in the impugned decision. Combining an independent claim with a dependent claims is one of the most straightforward amendments that a patent proprietor could carry out. The resulting independent claim can hardly bring about overly complex subject-matter, since that subject-matter as such was already present in the proceedings. Moreover, the opponent raised objections to the subject-matter of that claim 2 in the statement of grounds (point 9), as appropriate under Article 12(2) RPBA. Finally, auxiliary request I was filed one month in advance of the oral proceedings. That gave the Board and the opponent some time to deal with it without any need to adjourn the oral proceedings.

Together with the filing of auxiliary request I the proprietors withdrew a number of other requests already in the proceedings, which the Board sees as a contribution to procedural economy.

Auxiliary request I is also prima-facie relevant, since it clearly addresses objections regarding lack of novelty and inventive step raised by the opponent to the main request previously on file, by limiting the subject-matter claimed.

The opponent's argument that the proprietors had provided no arguments on novelty and inventive step at the time of filing of auxiliary request I is not decisive. It is primarily the opponent's duty to raise objections to claims held allowable by the Opposition Division in the impugned decision.

For these reasons the Board admits auxiliary request I into the proceedings under Article 13(1) and (3) RPBA.

4. Article 123(2) EPC

4.1 The subject-matter of the claim of auxiliary request I is generally derived from claims 1 to 3, page 4, line 15 to page 5, line 2, page 7, lines 1 to 3 and figures 2 and 3 of the application as originally filed.

More particularly, a basis for the "disposable tubing set [...] adapted for engagement with the continuous renal replacement monitor" is provided on page 4, line 22 to page 5, line 2 and claim 2; a basis for a dialyser comprised in the disposable tubing set is on page 7, lines 1 to 3 and figures 2 and 3, and a basis for the blood tube segment and its location relative to the other elements of the continuous renal replacement

therapy system is provided on page 4, lines 15 to 22.

4.2 The opponent argued in essence that the combination of these latter features constituted an unallowable intermediate generalisation, since they had been picked out of context.

The Board does not share this view. In the application as originally filed there is neither an explicit nor an implicit disclosure that these features of the disposable tubing set should be technically inextricably linked with other non-claimed features. On the contrary, they are explicitly recited as different aspects of the invention (page 4, line 15 to page 5, line 2) and, in particular as far as the presence of the dialyser as part of the disposable tubing set is concerned, consistently described independently in relation to the figures (page 7, lines 1 to 3). This provides the skilled person with the implicit information that they may or may not be combined with the features of the invention as defined in the broadest independent claim of the application as originally filed, in order to achieve one or more different technical effects related to those different aspects.

4.3 The opponent also argued that in the application as originally filed the blood warmer was defined as "designed to engage and hold" the blood tube segment "to transfer heat at a closely controlled temperature", which was no longer present in the claim of auxiliary request I.

The Board observes that for the skilled person the definition of a "blood tube segment (100) engaged with the blood warmer (20)" in the claim of auxiliary

request I does not add any technical content to the expression "a blood warmer designed to engage and hold a disposable blood tube segment". That definition simply limits the scope of the claim to the engaged configuration originally disclosed. As far as the term "hold" is concerned, the Board does not see how its omission could change the technical meaning with respect to the analogous term "engaged" employed in the claim. In the normal meaning of the terms, two elements engaged with one another are also held together. The application as originally filed does not provide any reason why this normal meaning should not apply in this specific case.

The omission of heat transfer taking place "at a closely controlled temperature" does not add undisclosed subject-matter either. In claim 1 of the application as originally filed a blood warmer was defined. This implies heat transfer. However, no mention of any "closely controlled temperature" at which the heat transfer should take place was present in that claim. This, in turn, makes clear that a "closely controlled temperature" for the heat transfer is not an essential feature of the invention, even in the light of the objective stated on page 4, lines 5 and 6 of the application as originally filed, that the local temperature of the blood had to be limited to levels which were not expected to damage the blood. This is implicit in the context of the claim, directed to a device for treatment of a patient by therapy.

4.4 The opponent's argument that the semicolon after the first mention of a dialyser in the claim implied that the blood tube segment defined afterwards was not a part of the disposable tubing set but only of the continuous renal replacement system is not convincing.

In the claim of auxiliary request I the blood tube segment is defined in the paragraph concerning the disposable tubing set, after the dialyser. In the claim a semicolon often appears as a punctuation mark separating the consecutive elements of a list. Moreover, the blood tube segment, in the form of an extension line, is claimed as being "intermediate the first (45) and the second (60) venous lines", which are clearly defined as parts of the disposable tubing set. It follows that, according to the claim, the blood tube segment is part of the disposable tubing set. The description of the patent does not suggest any other interpretation either. A basis for a disposable blood tube segment being part of the disposable tubing set is provided on page 4, lines 15 to 18 in combination with page 4, line 18 to page 5, line 2 and figure 3 of the application as originally filed.

4.5 The opponent's argument relating to the claim of auxiliary request I defining a specific assembly state of the system, which could only be realised during a specific method of operation of the device not disclosed in the application as originally filed, is not convincing either.

The claim defines a system in which some elements are connected to each other and others are simply suitable for connection to each other. In other words, as the proprietors submitted, the claim is drafted in terms of both structural and functional features of the system.

As far as the connections are specifically concerned, compared with the system defined in the combination of claims 1 to 3 of the application as originally filed, the system according to the claim of auxiliary request I additionally requires that the extension line

be actually connected to the blood warmer and the disposable tubing set. In the Board's view, the claim does not require that the detector for protecting against air embolism and the venous line clamp be actually mounted on the disposable tubing set. The terms "flow communication", "downstream" and "upstream" in the claim are to be interpreted as functional references to the intended condition of use.

A configuration with the claimed connections of the extension line is clearly disclosed in figure 3 of the application as originally filed. Moreover, the Board notes that the claim is directed to the system as such, not to a method of operating the system. The application as originally filed does not disclose that there has to be a specific assembly state of the elements of the system. On the contrary, it shows different possible configurations with different connections between the claimed elements. For example, in the configuration of figure 1 the disposable tubing set is not connected to the continuous renal replacement therapy monitor, whereas in the configurations of figures 2 and 3 the disposable tubing set is connected to the continuous renal replacement therapy monitor, respectively without and with engagement with the blood warmer. In the application as originally filed the specific relative positions and engagements between the elements depicted in figure 3 are therefore presented as optional, according to the intended condition of use. It follows that the connections of the extension line defined in the claim of auxiliary request I, which necessarily result in a limitation of the claimed system to only some of all the possible configurations according to the original disclosure, does not present the skilled person with information not directly and unambiguously derivable

from the application as originally filed.

4.6 The opponent further argued that a configuration with "a separable connector pair (50, 55) intermediate the first venous line (45) to the second venous line (60)" in which, at the same time, halves 50 and 55 of the separable connector pair were connected to the extension line was not disclosed in the application as originally filed.

This argument ignores the fact that, in the claim, the separable connector pair is further defined as "being separated". Hence, the presence of the extension line connected to respective halves of the connector pair does not have any influence on the position of the separable (and separated) connector pair still being "intermediate the first venous line to the second venous line". The features concerned are therefore fully supported by claims 2 and 3 of the application as originally filed.

4.7 It follows that the claim of auxiliary request I complies with Article 123(2) EPC.

5. Article 123(3) EPC

The claim of auxiliary request I has clearly been restricted in scope compared with claim 1 of the patent as granted, as several limiting features have been added and no features have been deleted.

The opponent's argument that a system in which the separable connector pair was connected to the extension line constituted an "aliud" to a system in which the separable connector pair permitted a separation of the first and the second venous lines, which, however, were

connected to each other, is not convincing.

It suffices to note that in claim 1 of the patent as granted, which defined the broadest scope of the claimed system, the separable connector pair was not even defined.

Hence, Article 123(3) EPC is complied with.

6. Article 84 EPC

The opponent raised a number of clarity objections to the subject-matter of the claim of auxiliary request I. In the Board's opinion, all of them fail.

6.1 More particularly, the opponent saw a contradiction between the definition of the disposable tubing set being "adapted for engagement" with the continuous renal replacement therapy monitor and the definition of some elements of the claimed system being connected to each other. The Board sees none. The general definition of a tubing set "adapted for engagement" with an element of the claimed system can subsequently be made more specific by adding the definition of actual engagements or connections of some elements of the tubing set to each other or to other elements of the claimed system. It is the proprietors' choice to draft the claim to a desired level of generality.

6.2 The opponent further argued that some specific functions of claimed structural features as well as specific structures for obtaining claimed functional features were not specified in the claim. The Board notes that, as long as the skilled person understands the claimed structures and functions, the issue may be at most one of broadness of the subject-matter claimed,

but not of clarity. As far as the venous line clamp is concerned, the claim defines that it is for receiving and co-operating with the fourth venous line of the disposable tubing set. The absence of a more specific definition of the interaction between the venous line clamp and the other elements of the system does not render the claimed feature unclear. It simply leaves open several possibilities for realising that interaction in the light of the teaching of the patent as a whole. Similarly, the feature of the extension line being "received by and cooperating with the blood warmer" does not specify the particular structure needed to implement it, as argued by the opponent. However, the skilled person, in the light of the teaching of the patent, has no difficulty in figuring out several possible structures, like the ones listed by the opponent itself, in accordance with the broad definition of the claim.

6.3 The terms "downstream" and "upstream" objected to by the opponent clearly indicate relative positions of the elements they relate to, by reference to the intended normal use of the device.

6.4 The definition of the separable connector pair being separated is not contradictory either. It simply specifies a connection between elements of the system, which does not exclude the inherent possibility of separating that same connection under certain circumstances. These circumstances are not claimed as such.

6.5 As regards the semicolon after the first mention of a dialyser in the claim, the same considerations as in point 4.4 above apply. It follows that the blood tube segment is clearly claimed as part of the disposable

tubing set.

6.6 For these reasons the requirements of Article 84 EPC are fulfilled by the claim of auxiliary request I.

7. Article 56 EPC

7.1 It is common ground that D37 is the closest prior art.

D37 is concerned with a comparative study of three methods for treating acute renal failure after cardiac operations. One of these methods involves a continuous venous hemofiltration system (from page 324, left column, first full paragraph), which is a particular continuous renal replacement therapy system. This system includes a continuous renal replacement therapy monitor (implicit, for the control of the various pumps and other components, in view of the fact that the system could be left under the control of a "bedside nurse" - page 324, right column, first full paragraph, third sentence) having a venous pressure transducer (pressure alarm described on page 324, right column, first full paragraph, second sentence), a detector for protecting against air embolism, and a blood warmer attached to the monitor (page 324, right column, first full paragraph, first sentence). In its disclosure of the blood warmer, D37 refers to the trademark "Hotline" of company "Level 1 Technologies Inc.".

7.2 A warmer with the same name is disclosed in more detail in D38, albeit in relation to a different treatment. D38 was filed after the opponent's reply to the proprietors' statement of grounds of appeal, but still well before the parties were summoned to oral proceedings. The proprietors correctly argued that different warmers could be covered by a single

trademark. However, in the present case, at a prima-facie level, the same trademark constitutes a convincing link between D37 and D38, possibly to be analysed in more depth when assessing inventive step. Nothing specific was provided by the proprietors to demonstrate the opposite. For these reasons the Board admits D38 into the proceedings under Article 13(1) RPBA.

7.3 The sole disclosure of a blood warmer in the continuous renal replacement therapy system of D37 (page 324, right column, first full paragraph, first sentence) reads:

"*Blood returning to the patient after the filter via the 'venous' lumen of the catheter passed through a drip chamber with an air bubble detector and finally a blood warmer (Hotline, Level 1 Technologies Inc., Rockland, Mass.).*"

It follows that D37 does not disclose that the blood warmer of the continuous renal replacement therapy system receives and co-operates with an extension line having at each end one half of a connector pair interconnected with the halves of the separable connector pair of the disposable tubing set.

Moreover, it is undisputed that D37 does not disclose the particular tubing set with first to fourth venous lines and a sample access site "intermediate" the second and third venous lines as defined in the claim of auxiliary request I.

7.4 The distinguishing feature of the claimed arrangement of the extension line connected to two halves of a separable connector pair has the technical effect that

the extension line can easily be replaced or even completely removed, for performing a therapy without it. This can be achieved by disconnecting the extension line and connecting the halves of the separable connector pair to one another.

As regards the claimed tubing set with the first to fourth venous lines and the sample access site "intermediate" the second and third venous lines, this has the technical effect that excess air and gases created by the warmer can be collected from the access site, as mentioned in column 5, lines 45 to 48 of the patent (corresponding to page 8, lines 22 to 24 of the application as originally filed). This is due to the position of the access site downstream from the blood warmer derivable from the claim of auxiliary request I. More particularly, the claim defines that the blood tube segment (in the form of the extension line received by the blood warmer) is connected to the halves of the separable connector pair, intermediate the first and second venous lines, and is upstream from the detector and the venous line clamp, which are adapted to receive the fourth venous line. It follows that the first to fourth venous lines according to the claim are to be interpreted as being disposed, in use, in that order along the direction of the flow. This is confirmed by the disclosure of the patent as a whole, as clearly derivable from figure 3, for example. Since the sample access site is claimed as being "intermediate the second venous line (60) and the third venous line (70)", it is necessarily in use downstream from the blood warmer engaging the extension line intermediate the first and second venous lines.

7.5 It follows that the distinguishing feature of the claimed arrangement of the extension line connected to

two halves of a separable connector pair addresses the objective technical problem of providing a continuous renal replacement therapy system permitting warming of the blood re-infused into the patient after treatment, in which that warming can controllably be tailored to the patient's needs, for example by providing extension lines of different lengths or doing away with the extension line altogether.

The distinguishing feature of the claimed tubing set, in particular the position of the sample access site downstream from the blood warmer, addresses the objective technical problem of providing a continuous renal replacement therapy system permitting warming of the blood re-infused into the patient after treatment, in which the warming can easily be controlled: due to the access site there is no need for a drip chamber after the warmer, which could cause undesired variable heat dispersion.

The problem formulated by the opponent in connection with the distinguishing feature of the claimed tubing set is not acceptable, since it merely recites the inherent function of the access site without any analysis of its purpose in the specific system as claimed. The opponent's argument that the problems associated with the two distinguishing features considered above are different is also not convincing. In the Board's view those problems are closely interrelated, since they both concern the optimisation of the warming process.

7.6 The opponent argued that the skilled person would combine the teachings of D38 and D1 with D37.

D38 is concerned with the optimisation of a warming process of fluid to be injected into a patient at slow flow rates (page 974, first column, fourth paragraph). The warmer disclosed in D38 would therefore be suitable for the system according to the claim of auxiliary request I, which also works at slow flow rates. D38 also discloses "Heated Delivery Tubing" (figure 1) which may be considered to be an extension line, since it is interposed between two other lines of "Delivery Tubing" by means of connectors. However, D38 does not disclose that the "Heated Delivery Tubing" is connected to two halves of a separable connector pair. It follows that, even combining D38 with D37, the subject-matter of claim I of auxiliary request I would not be arrived at.

D1 is concerned with a reusable tubing set for dialysis (column 5, lines 11 to 33), stressing the advantages of this reusability (column 4, line 43 to column 5, line 10). The skilled person would not consider this document for solving a problem specifically concerned with the optimisation of the warming of blood re-infused into a patient after a treatment, the warming process employing a disposable tubing set, since the problem is not addressed at all, either explicitly or implicitly, in D1.

7.7 For these reasons, the subject-matter of the claim of auxiliary request I is inventive (Article 56 EPC).

8. Rule 42 EPC

During oral proceedings the proprietors filed an adapted description. In particular, document D37 is cited at the end of paragraph [0011] and paragraphs [0014] and [0015] of the description of the patent as granted have been amended in order to bring them into line with the claim of auxiliary request I.

The opponent argued that the references to the figures in paragraphs [0016] and [0017] were not in line with the claim of auxiliary request I. The Board notes that paragraph [0014] makes clear that the invention is defined in the claim, whereas paragraphs [0016] and [0017] simply state that the invention or a preferred embodiment will be described "with reference to" some figures. Hence, especially in the light of paragraph [0014], no direct contradiction is apparent between paragraphs [0016] and [0017] and the subject-matter claimed.

Moreover, if a contradiction were present, it would not have been caused by the amendments made during the opposition proceedings, since the same paragraphs were present in the patent as granted, and figures 6 and 7 showing the mounting of a blood warmer on the continuous renal replacement therapy system did not directly relate to the subject-matter of the claims of the patent as granted either. Since the objection to those paragraphs [0016] and [0017] is not related to any ground of opposition, it must fail for that reason alone.

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 on the basis of:

   - claim 1 of auxiliary request I filed with letter dated 28 February 2017;

   - adapted description, columns 1 to 7, filed during oral proceedings; and

   - figures 1 to 7 of the patent as granted.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated