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# Datasheet for the decision of 17 March 2015

**Case Number:** T 0722/11 - 3.3.07

**Application Number:** 00927004.2

**Publication Number:** 1176969

**IPC:** A61K33/42, A61K33/14, A61K33/06, A61K31/70, A61P7/08

**Language of the proceedings:** EN

**Title of invention:**
SUBSTITUTION INFUSION FLUID AND CITRATE ANTICOAGULATION

**Patent Proprietor:**
Nikkiso Co., Ltd.

**Opponents:**
Fresenius Medical Care Deutschland GmbH
B. Braun Melsungen AG

**Headword:**

**Relevant legal provisions:**
EPC Art. 123(2), 56
RPBA Art. 13(1)

**Keyword:**
Amendments - added subject-matter
(yes) Main request and auxiliary requests 1 to 7
Inventive step - (no) auxiliary requests 8 to 10
Late-filed auxiliary requests - admitted (no)

**Decisions cited:**

**Catchword:**

Europäisches Patentamt
European Patent Office
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**Beschwerdekammern**
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**Case Number: T 0722/11 - 3.3.07**

# D E C I S I O N
# of Technical Board of Appeal 3.3.07
# of 17 March 2015

| | |
|---|---|
| **Appellant:** (Patent Proprietor) | Nikkiso Co., Ltd.<br>Yebisu Garden Place Tower<br>20-3, Ebisu 4-chome<br>Shibuya-ku<br>Tokyo 150-6022 (JP) |
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| **Appellant:** (Opponent 1) | Fresenius Medical Care Deutschland GmbH<br>Else-Kröner-Strasse 1<br>61352 Bad Homburg (DE) |
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| **Decision under appeal:** | **Interlocutory decision of the Opposition Division of the European Patent Office posted on 21 January 2011 concerning maintenance of the European Patent No. 1176969 in amended form.** |

**Composition of the Board:**

| | |
|---|---|
| **Chairman** | J. Riolo |
| **Members:** | A. Usuelli |
| | P. Schmitz |

## Summary of Facts and Submissions

I. The appeals of the patent proprietor and the opponent lie from the decision of the opposition division announced at the oral proceedings on 29 November 2010 concerning the maintenance of European patent 1 176 969 in amended form.

The application from which the patent originated was filed on 2 November 2000. Claim 1 of the original application read as follows:

"1. Aqueous substitution infusion fluid for hemofiltration comprising

— between 0.2 and 1 mmol/L of dihydrogen phosphate ions;
— between 70 and 130 mmol/L of sodium ions;
— between 1.6 and 2.6 mmol/L of calcium ions;
- between 0.25 and 1.25 mmol/L of magnesium ions;
— between 1 and 4 mmol/L of potassium ions;
- between 3 and 11.5 mmol/L of glucose;
- below 5.5 mmol/L of acetate ions; and
- below 5.5 mmol/L of bicarbonate ions."

The patent was granted with 19 claims. Independent claim 1 related to a substitution infusion fluid whose composition differed from the composition defined in claim 1 of the original application in that:

a) the feature "below 5.5 mmol/L of bicarbonate ions" was deleted, and
b) the feature "and chloride ions to keep electrochemical balance" was added at the end of the claim.

II. The patent was opposed under Article 100(a) and (c) EPC on the grounds that its subject-matter lacked novelty and inventive step and it extended beyond the content of the application as filed.

III. The documents filed during the opposition proceedings included the following:

D3: WO90/15612
D5: Kidney International, Vol. 55 (1999), 1991-1997
D9: European Pharmacopoeia 1997, 921-927
D13: US 5,709,993

IV. The decision was based on the patent as granted and on three sets of claims filed during the oral proceedings as first to third auxiliary requests.

The third auxiliary request was considered by the opposition division to comply with the requirements of the Convention. The subject-matter of claim 1 of that request, read as follows:

"1. Aqueous substitution infusion fluid for hemofiltration using a citrate anticoagulant solution comprising between 15 and 135 mmol/L of citric acid and between 80 and 550 mmol/L of trisodium citrate comprising:

— between 0.2 and 1 mmol/L of dihydrogen phosphate ions;
— between 70 and 130 mmol/L of sodium ions;
— between 1.6 and 2.6 mmol/L of calcium ions;
- between 0.25 and 1.25 mmol/L of magnesium ions;
— between 1 and 4 mmol/L of potassium ions;
- between 3 and 11.5 mmol/L of glucose;
- below 5.5 mmol/L of acetate ions;

- below 5.5 mmol/L of bicarbonate ions
- and chloride ions to keep electrochemical balance"

V. According to the decision under appeal:

a) Claim 1 of the granted patent did not comply with the requirements of Article 123(2) EPC in view *inter alia* of the deletion of the feature concerning the bicarbonate ions concentration.

b) The first and second auxiliary requests did not comply with the requirements of Article 56 EPC.

c) Document D9 was the closest prior art for the assessment of inventive step of claim 1 of auxiliary request 3. The technical problem was to be seen in "the provision of a hemofiltration solution suitable for hemofiltration with the citrate anticoagulation fluid specified in claim 1". The solution of claim 1 was not suggested by the teaching of D9 considered alone, or in combination with the other relevant documents.

VI. Both parties lodged an appeal against that decision. With the statement setting out the grounds of appeal dated 27 May 2011 the appellant-patent proprietor requested that the decision under appeal be set aside and the patent be maintained on the basis of the granted claims, or alternatively that the patent be maintained on the basis of auxiliary requests 1 to 10 filed therewith.

During the oral proceedings held on 17 March 2015 the appellant-patent proprietor submitted two new requests designated respectively as auxiliary request 2-1 and

auxiliary request 11, and requested his requests be considered in the following order:

main request (granted patent), auxiliary request 2-1 (filed during oral proceedings), auxiliary requests 8 to 10 (filed on 27 May 2011), auxiliary requests 1 to 7 (filed on 27 May 2011), auxiliary request 11 (filed during oral proceedings).

VII. The subject-matter of the relevant claims of the auxiliary requests, in the order established by the appellant-patent proprietor (see VI above), can be summarised as follows:

a) Claim 1 of auxiliary request 2-1 differed from claim 1 of the granted patent (see point I above) in the addition of a feature indicating that the amount of bicarbonate ions was below 5.5 mmol/L.

b) Claim 1 of auxiliary requests 8 and 9 was identical to claim 1 of the request maintained by the opposition division (see point IV above).

c) Claim 1 of auxiliary request 10 read as follows:

"1. Aqueous substitution infusion fluid for hemofiltration using a citrate anticoagulant solution comprising between 15 and 135 mmol/L of citric acid and between 80 and 550 mmol/L of trisodium citrate comprising:

— between 0.4 and 0.8 mmol/L of dihydrogen phosphate ions;
— between 90 and 110 mmol/L of sodium ions;
— between 1.8 and 2.3 mmol/L of calcium ions;
- between 0.5 and 1 mmol/L of magnesium ions;

— between 1.8 and 3.5 mmol/L of potassium ions;
- between 5.5 and 7.5 mmol/L of glucose;
- below 5.5 mmol/L of acetate ions; and
- below 5.5 mmol/L of bicarbonate ions
- and chloride ions to keep electrochemical balance"

d) Claim 1 of auxiliary requests 1 to 7 was derived from claim 1 of the granted patent. The feature "below 5.5 mmol/L of bicarbonate ions" was not present in any of these claims.

e) Claim 1 of auxiliary request 11 differed from claim 1 of the application in the addition of the following feature at the end of the claim:

"...- and chloride ions to keep electrochemical balance - combined with a citrate anticoagulant solution comprising between 15 and 135 mmol/L of citric acid and between 80 and 550 mmol/L of trisodium citrate."

VIII. As far as relevant for the present decision, the arguments of the appellant-opponent can be summarised as follows:

*a) Main request and auxiliary requests 1 to 7 - Article 123(2) EPC*

The aqueous substitution infusion fluid defined in claim 1 of the original application was characterised *inter alia* by a concentration of bicarbonate ions below 5.5 mmol/L. This feature was no longer present in claim 1 of the main request and of auxiliary requests 1 to 7. Accordingly, these requests covered also infusion fluids containing more than 5.5 mmol/L bicarbonate ions. The deletion of the feature concerning the amount

of bicarbonate ions was therefore against the requirements of Article 123(2) EPC.

Claim 16 of the main request did not contain any limitation as to the composition of the citrate anticoagulant solution. However, in the original application this solution contained defined amounts of citric acid and trisodium citrate. In claim 18 of the main request, the concentration of 38 mmol/L had no basis in the original application. Thus, also the amendments introduced in claims 16 and 18 of the main request did not comply with the requirements of Article 123(2) EPC.

*b) Admittance of auxiliary request 2-1*

The amendments introduced in this request addressed objections which the opponent had already raised during the first-instance proceedings. Hence, according to Article 12(4) RPBA, auxiliary request 2-1 should have been presented during the opposition stage. This request was therefore not to be admitted.

*c) Claim 1 of auxiliary requests 8 to 10 - Article 56 EPC*

The closest prior art was represented by document D9. The infusion fluid defined in claim 1 of auxiliary requests 8 and 9 differed from the composition disclosed in Table 861-1 of D9 only on account of the presence of dihydrogenphosphate ions. The technical problem was to improve the substitution infusion fluid known from D9. Document D5 taught the importance of monitoring during the hemofiltration various blood parameters including the level of phosphate. A person skilled in the art noticing a reduction in the amount

of dihydrogenphosphate ions would have obviously considered adding them to the substitution infusion fluid in order to restore the normal levels. The use of a citrate anticoagulant solution during the process of hemofiltration concerned a different technical problem unrelated to the problem of providing a substitution infusion fluid. There was no relationship between the composition of the anticoagulant solution and the composition of the infusion fluid. In particular, the presence of citrate ions in the anticoagulant solution did not affect the concentration of dihydrogenphosphate ions. The description of the patent did not contain any teaching in this respect. Moreover, anticoagulant solutions containing citrate ions useful in processes involving an extracorporeal blood circulation were already known from D13. An anticoagulant solution identical to the one disclosed in the patent in suit was disclosed in document D3.

The substitution infusion fluid defined in claim 1 of auxiliary request 10 differed from the composition of D9 also on account of the amount of sodium. However, there were no improvements associated with the different concentration of this ion. The arguments submitted with respect to claim 1 of auxiliary requests 8 and 9 applied also to claim 1 of auxiliary request 10.

*d) Admittance of auxiliary request 11*

Claim 1 referred to a combination between the substitution infusion fluid and the anticoagulant solution. It related to a different subject as compared to claim 1 of the other requests. It was questionable whether it complied with the requirements of Articles 123(3) and 84 EPC. For these reasons, the

late-submitted auxiliary request 11 was not to be admitted into the proceedings.

IX. As far as relevant for the present decision, the arguments of the appellant-patent proprietor can be summarised as follows:

*a) Main request and auxiliary requests 1 to 7 - Article 123(2) EPC*

The feature "below 5.5 mmol/L of bicarbonate ions" was not explained as essential in the original application. It rather represented an optional feature of the invention. This was clear for instance from the passages of the original application starting from page 6 line 34 and page 7 line 19, in which examples of substitution infusion fluids were disclosed without any mention as to the presence of bicarbonate ions. The feature concerning the bicarbonate was furthermore not essential for the function of the substitution fluid. Its replacement or removal required no real modification of other features. The deletion of this non-essential feature was not in breach of Article 123(2) EPC.

*b) Admittance of auxiliary request 2-1*

Compared to the main request, auxiliary request 2-1 contained amendments in claims 1, 16 and 18. These amendments were in response to some objections raised by the appellant-opponent under Article 123(2) EPC. Auxiliary request 2-1 was to be admitted into the appeal proceedings.

*c) Claim 1 of auxiliary requests 8 to 10 - Article 56 EPC*

In claim 1 of auxiliary requests 8 and 9, it was indicated that the substitution infusion fluid for hemofiltration was to be used in combination with an anticoagulant composition containing citric acid and trisodium citrate in specific amounts. Document D9 made no reference to the use of anticoagulant solutions. The citrate anticoagulant solution disclosed in D3 had a different use, namely preventing blood's coagulation during storage. This document did not refer to processes of hemofiltration. The same was true for document D13. Furthermore, in the process disclosed in this document, the prevention of the blood's coagulation required also the addition of heparin. Hence, the prior art did not suggest using in a process for hemofiltration a substitution infusion fluid containing dihydrogenphosphate ions in combination with an anticoagulant solution containing citrate ions. The combination of the two liquids made it possible to prevent the occurrence of abnormalities in the concentration of electrolytes. The two compositions were working in a synergistic manner. The presence of dihydrogenphosphate ions in the substitution infusion fluid was in relation to the specific composition of the anticoagulant. Document D5 disclosed the use of a citrate-based solution as anticoagulant in a process of hemofiltration. However, this document did not suggest adding dihydrogenphosphate ions in the substitution infusion fluid.

The specific substitution infusion fluid defined in auxiliary request 10 represented a preferred embodiment of the invention. The skilled person had to carry out various modifications to the composition of D9 in order to arrive at the infusion fluid defined in this

request. However, optimising the balance of the different electrolytes was a difficult task.

*d) Admittance of auxiliary request 11*

It was clear from the application as originally filed that the substitution infusion fluid and the anticoagulant solution were to be used in combination. This was evident also from the wording of granted claim 16. The wording of claim 1 of auxiliary request 11 underlined the fact that during the process of hemofiltration the two compositions were combined. The subject-matter of the claim was clearly defined. Auxiliary request 11 was to be admitted into the appeal proceedings.

X. The appellant-patent proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted (main request), alternatively that the patent be maintained on the basis of auxiliary request 2-1, filed during the oral proceedings, or auxiliary requests 8 to 10 or auxiliary requests 1 to 7 filed with letter of 27 May 2011, or auxiliary request 11, filed during the oral proceedings, the requests to be decided in this order.

XI. The appellant-opponent requested that the patent be revoked.

## Reasons for the Decision

*Main request (granted patent)*

1. Article 123(2) EPC

1.1 In its decision the opposition division came to the conclusion that the amendments introduced in claim 1 of the granted patent did not comply with the requirements of Article 123(2) EPC. One of the deficiencies noted by the division was the omission of the feature "below 5.5 mmol/L of bicarbonate ions" which was present in claim 1 of the application as filed.

1.2 The Board notes that the feature "below 5.5 mmol/L of bicarbonate ions" expresses a requirement that the aqueous substitution fluid has to satisfy, namely it cannot contain more that 5.5 mmol of bicarbonate per litre. Such a requirement is expressed not only in claim 1 of the application as filed but also in the description, e.g. page 4, lines 37-38.

1.3 The appellant-patent proprietor has argued that the feature concerning the concentration of bicarbonate ions does not represent an essential feature of the invention and therefore it can be omitted from the claim. In this respect he has referred to some passages of the description disclosing compositions according to the invention in which no mention is made of the concentration of bicarbonate ions (page 6, line 34 to page 7, line 4 and page 7, lines 19 to 29)

Contrary to the position expressed by the appellant-patent proprietor, the Board considers that the absence of any indication as to the amount of bicarbonate ions cannot be interpreted to imply that these ions can be present in any amount. It rather indicates that in the compositions disclosed in the passages mentioned above the bicarbonate ions are absent, which is consistent with the requirement that this substance cannot exceed the amount of 5.5 mmol/L. In this respect it is noted that according to the description (page 4, line 36) the

amount of bicarbonate ions is preferably between 0 and 3.1 mmol/L. This means that the absence of bicarbonate ions is expressly mentioned in the application as a preferred embodiment of the invention.

1.4 The omission of the feature "below 5.5 mmol/L of bicarbonate ions" has the consequence that the claimed compositions no longer need to fulfil the requirement concerning the maximum amount of bicarbonate ions. It follows that as a result of the amendment, the subject-matter of claim 1 relates also to compositions which were not part of the invention as described in the application as filed. In other words claim 1 contains subject-matter extending beyond the content of the application as filed.

The Board concludes from the above that the main request does comply with the requirements of Article 123(2) EPC.

*Auxiliary request 2-1*

2. Admittance into the appeal proceedings

2.1 Auxiliary request 2-1 was submitted by the appellant-patent proprietor during the oral proceedings before the Board. The admittance of this request is at the Board's discretion according to Article 13(1) RPBA. The discretion is to be exercised in view *inter alia* of the current state of the proceedings and the need for procedural economy.

2.2 Claim 1 of auxiliary request 2-1 differs from claim 1 of the main request in the additional requirement that the amount of bicarbonate ions is below 5.5 mmol/L. Further amendments introduced in auxiliary request 2-1

relate to the introduction in claim 16 of the composition of the anticoagulant solution and the modification in claim 18 of the range defining the concentration of citric acid.

The appellant-patent proprietor argued, in justification of the late filing of this request, that the amendments included therein were in response to objections raised by the appellant-opponent under Article 123(2) EPC.

2.3 The objections referred to by the appellant-patent proprietor were included in the statement setting out the grounds of appeal filed by the appellant-opponent on 31 May 2011, i.e. more than three years before the date of oral proceedings. Furthermore, the minutes of the oral proceedings before the opposition division (point 2.1) indicate that these objections were already raised in the course of the first-instance proceedings, as declared also by the appellant-opponent during the hearing before the Board (see point VIII b) above).

2.4 The appellant-patent proprietor had therefore plenty of time to file before the date of oral proceedings one or more requests addressing the objections under Article 123(2) EPC. Accordingly, in the interests of procedural economy the Board exercises its discretion not to admit auxiliary request 2-1 since it was filed without any valid reason at a late stage in the proceedings.

*Auxiliary request 8*

3. Inventive step

3.1 The subject-matter of claim 1 relates to a substitution infusion fluid for use in a process of blood's hemofiltration, which is a particular form of renal-replacement therapy widely used in intensive care units ([0002]). During hemofiltration, the patient's blood is passed over a semipermeable membrane mimicking the natural filtering function of a kidney. This leads to a loss of fluids from the blood and a net removal of substances such as ions and trace elements ([0005] and [0012]). In order to keep constant the blood's volume and the concentration of important substances such as electrolytes, a substitution infusion fluid containing electrolytes and other molecules is added to the blood stream in the extracorporeal circuit before it re-enters the patient's vein. A further solution is introduced in the extracorporeal circuit in order to prevent coagulation of the blood [0006].

The patent in suit addresses the problem of providing a substitution infusion fluid for hemofiltration which is specifically adapted to be used in hemofiltration processes using a citrate solution as anticoagulant [0013].

Closest prior art

3.2 The Board agrees with the parties and with the opposition division that document D9 represents the closest prior art. This document is an extract from the European pharmacopeia of 1997. Section "1997:0861" (page 925) relates to solutions for hemofiltration. It is explained that these solutions are preparations containing various electrolytes with a concentration close to the electrolytic composition of plasma. Although the expression "substitution infusion fluid" is not used in D9, it was not disputed by the

parties that the compositions disclosed therein are indeed substitution infusion fluids and therefore used for the same purpose as the solutions defined in claim 1 of the patent in suit.

3.3 A typical composition of a solution for hemofiltration is disclosed in Table 861-1 of D9 (page 925). The substitution infusion fluids of the patent in suit differ from the composition of Table 861-1 in that they contain between 0.2 and 1 mmol/L dihydrogen phosphate ions, while this substance is absent from the composition of D9. This finding was not disputed by the parties.

Technical problem

3.4 Starting from the disclosure of D9, the technical problem underlying the invention can be defined as the provision of a substitution infusion fluid for a process of hemofiltration in which a citrate solution is used as anticoagulant.

The patent does not contain any experimental data relating to tests carried out using the compositions of the patent in suit. The Board sees however no reasons for questioning that these compositions can be used in processes of hemofiltration in general and in particular those using a citrate solution as anticoagulant. Nor has the appellant-opponent raised any doubts in this respect.

Accordingly, the Board considers that the technical problem defined above has been solved by the provision of the substitution infusion fluids of claim 1.

Obviousness

3.5 As discussed above (see 3.1), in order to prevent blood's coagulation during hemofiltration, an anticoagulant solution is added to the blood in the extracorporeal circuit. Documents D5 (page 1991, right column, second and third paragraph) and D13 (column 1, lines 36 to 53) indicate that heparin and citrate are the most commonly used agents for preventing coagulation in hemofiltration processes. This is acknowledged also in the "Background Art" section of the patent in suit (paragraphs [0006] and [0007]).

Document D9 does not contain any indication as to the anticoagulant composition to be used in combination with the composition disclosed in Table 861-1. In the Board's view, the absence of any information as to possible restrictions in relation to the anticoagulant solution, such as problems of specific incompatibility, would be regarded by the skilled person as an indication that the composition of Table 861-1 can be used in a process of hemofiltration no matter the anticoagulant used. In particular, the composition would be considered suitable for processes of hemofiltration using citrate as anticoagulant.

3.6 Since the passage of the blood over the membrane of the apparatus for hemofiltration causes a removal of various substances, it is important, as underlined by the appellant-opponent, to monitor the changes in the concentrations of the serum's electrolytes and of other molecules having important physiological functions. This could be done for instance by analysing the composition of the blood after it has passed over the membrane, or by analysing the filtrate, i.e. the mixture of substances filtered out by the membrane.

3.7 By monitoring the serum composition, a skilled person would immediately observe any relevant deviation from standard levels of the concentrations of electrolytes or of any other substance. Hence, any shortage of dihydrogen phosphate ions caused by the hemofiltration therapy would be noticed and if necessary remedied.

Since the main function of the substitution infusion fluid is to restore the physiological levels of the molecules removed by hemofiltration, the skilled person would remedy a deficiency of dihydrogen phosphate ions by adding them to a standard substitution infusion fluid such as the one disclosed in Table 861-1 of D9. This would lead the skilled person to the solution of the problem as claimed in claim 1.

3.8 The appellant-patent proprietor reiterated during the oral proceedings the argument that the composition of the substitution infusion fluid of the patent in suit was adjusted on the basis of its use in combination with a specific citrate anticoagulant solution and that neither D9 nor the other relevant documents related to processes of hemofiltration using the same anticoagulant solution.

3.9 With respect to this argument the Board observes that the patent does not contain any experimental data relating to tests carried out using the substitution infusion fluid of the patent in suit or the composition of D9. This absence of data does not allow the Board to assess whether and how the substitution infusion fluid of the patent in suit is "tailored" to the specific anticoagulant solution used, while the composition of D9 should not be considered suitable for use in combination with the same anticoagulant solution. As pointed out above, the infusion fluid of the patent in

suit differs from the composition of D9 only in the presence of dihydrogen phosphate ions. The patent however does not contain any data linking the use of a citrate anticoagulant solution with the blood concentration of dihydrogen phosphate ions. In other words there is no proof for an effect of the anticoagulant solution on the dihydrogen phosphate ions, which represent the distinguishing feature over D9. Such an effect is also not derivable from the general teaching of the patent. Indeed some considerations with regard to the effects of the citrate ions on the concentration of the electrolytes are provided in paragraph [0011]. However, what is affirmed therein is that "citrate ions bind to positively charged metal ions like calcium, magnesium, iron, zinc, copper, and manganese" and as a consequence these ions are partly removed in the artificial kidney. Hence, no mention is made of any possible effect of the citrate on the negatively charged ions such as the dihydrogen phosphate ions.

The argument of the appellant-patent proprietor is therefore not convincing.

3.10 The above considerations are also not affected by the argument that none of the cited prior-art documents disclose, in the context of a hemofiltration therapy, a citrate-based anticoagulant solution having the same concentration of citric acid and trisodium citrate of the anticoagulant composition defined in claim 1.

As explained above, the patent does not contain any experimental data which could allow an evaluation of the effects of the anticoagulant solution on the hemofiltration process and in particular on the concentration of the dihydrogen phosphate ions. Thus,

the fact that the exact composition of the citrate solution used in the patent in suit may differ from the citrate solution used for instance in D13, does not affect the validity of the conclusions made in paragraph 3.9 above.

3.11 Independently from any consideration relating to the anticoagulant solution, the Board emphasises that monitoring the concentration of electrolytes or other important molecules in the course of a renal-replacement therapy such as hemofiltration, is a procedure that a skilled person would need to carry out in order to check the effectiveness and safety of the therapy itself. In the Board's view, this would be made no matter the anticoagulant solution used. Hence, any shortage of ions or any other substance would be noticed independently of the specific solution used for preventing blood's coagulation.

3.12 For the above reasons, the Board comes to the conclusion that the subject-matter of claim 1 does not meet the requirements of Article 56 EPC.

*Auxiliary request 9*

4. Inventive step

Claim 1 of this request is identical to claim 1 of the auxiliary request 8. Hence, also auxiliary request 9 does not meet the requirements of Article 56 EPC.

*Auxiliary request 10*

5. Inventive step

5.1 Document D9 again represents the closest prior art for the assessment of inventive step of the subject-matter of claim 1.

5.2 In claim 1 of this request, the ranges defining the concentrations of dihydrogen phosphate, sodium, calcium, magnesium, potassium and glucose have been narrowed as compared to the corresponding ranges of auxiliary request 8. As a consequence of these amendments, in addition to the dihydrogen phosphate ions, also the sodium ions have a concentration (90 to 110 mmol/L) which lies outside of the concentration's range disclosed in Table 861-1 of D9 (125 to 150 mmol/L).

5.3 In the absence of any experimental data relating to the substitution infusion fluid of claim 1 of this request, the technical problem remains the one defined in respect of auxiliary request 8, namely the provision of a substitution infusion fluid for a process of hemofiltration in which a citrate solution is used as anticoagulant.

5.4 The considerations made with regard to auxiliary request 8 (see in particular points 3.5 to 3.11) also apply in the context of this request. In particular, the Board considers that monitoring the concentrations of blood's ions would lead the skilled person to observe any relevant anomaly in the amount of sodium and to correct it by adjusting the composition of the substitution infusion fluid.

Moreover, as for the composition of the auxiliary request 8, the patent does not contain any evidence supporting the assertion of the appellant-patent proprietor that the substitution infusion fluid has a

composition adjusted to the combined use with a specific citrate anticoagulant solution (see points 3.8 to 3.10 above).

5.5 In the light of the above the Board concludes that the auxiliary request 10 does not involve an inventive step.

*Auxiliary requests 1 to 7*

6. Article 123(2) EPC

Claim 1 of all these requests differs from claim 1 of the application as filed *inter alia* in the deletion of the feature "below 5.5 mmol/L of bicarbonate ions".

Thus, the subject-matter of claim 1 of these requests fails to comply with the requirements of Article 123(2) EPC for the same reasons given with respect to the main request (see point 1 above).

*Auxiliary request 11*

7. Admittance into the appeal proceedings

7.1 Auxiliary request 11 was submitted during the oral proceedings before the Board of appeal. Claim 1 of this request relates to a substitution infusion fluid "combined with a citrate anticoagulant solution".

7.2 The Board agrees with the appellant-opponent that the subject-matter of claim 1 appears to relate to a single composition deriving from the combination of the substitution infusion fluid with the anticoagulant solution. Such a reading of the claim is however not supported by the whole application, which never refers

to the substitution infusion fluid and to the anticoagulant solution as a single product, but rather as two distinct compositions which are added to the extracorporeal blood circuit at two different points, i.e. respectively after and before the passage of the blood over the membrane (see Figure 1). The interpretation of claim 1 in the light of the description appears therefore problematic. Furthermore, since neither the original application nor the patent as granted relates to a product deriving from the combination of the substitution infusion fluid with the anticoagulant solution, strong doubts exist also with regard to the requirements of Article 123(2) and (3) EPC.

7.3 Besides these considerations, the Board observes that the conclusions on the issue of inventive step made above already take due account of the fact that the substitution infusion fluid is used in a hemofiltration process in combination with a specific citrate anticoagulant solution. It is therefore not clear how the subject-matter of auxiliary request 11 could overcome the objections under Article 56 EPC.

7.4 It follows from the above that the late-submitted auxiliary request 11 does not solve *prima facie* the previously raised objection under Article 56 EPC and also raises new issues. This is considered against the need for procedural economy mentioned in Article 13(1) RPBA.

Auxiliary request 11 is therefore not admitted into the proceedings.

**Order**

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

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated