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Datasheet for the decision of 12 June 2015

Case Number: T 0024/12 - 3.2.02

Application Number: 02782066.1

Publication Number: 1450879

IPC: A61M1/16

Language of the proceedings: EN

Title of invention:
METHOD OF PRIMING A DIALYSIS MACHINE

Patent Proprietor:
Gambro Lundia AB

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 114(2), 123(2), 123(3)

Keyword:
Amendments - added subject-matter (no)
Grounds for opposition -
fresh ground for opposition in appeal proceedings (yes) -
admissibility (no)
Late-submitted material - document admitted (yes)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:
G 0010/91

Catchword:

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Case Number: T 0024/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 12 June 2015

Appellant: (Patent Proprietor)	Gambro Lundia AB Box 10101 220 10 Lund (SE)
Representative:	Roberts, Mark Peter J A Kemp 14 South Square Gray's Inn London WC1R 5JJ (GB)
Respondent: (Opponent)	Fresenius Medical Care Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg (DE)
Representative:	Bobbert, Cornelius Bobbert & Partner Patentanwälte PartmbB Postfach 1252 85422 Erding (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 21 October 2011 revoking European patent No. 1450879 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	D. Ceccarelli
	C. Körber

Summary of Facts and Submissions

I. The patent proprietor has appealed the Opposition Division's decision, dispatched on 21 October 2011, to revoke European patent No. 1 450 879.

II. The Opposition Division revoked the patent on the ground that the subject-matter of claim 1 of the pending requests lacked novelty over document:

D4: EP-A-1 097 724.

III. The notice of appeal was received on 21 December 2011. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 28 February 2012.

IV. The respondent's (opponent's) reply to the statement of grounds was received on 13 July 2012. Inter alia, it contained objections to the subject-matter of claim 1 of the main request in respect of added subject-matter, lack of novelty and lack of inventive step. It also contained an objection in respect of an exception to patentability.

V. The Board summoned the parties to oral proceedings and set out its provisional opinion in a communication dated 18 March 2015. The oral proceedings were held on 12 June 2015.

VI. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or, in the alternative, one of the first to fourth auxiliary requests, all filed with letter dated 28 February 2012, or one of the fifth and sixth auxiliary requests, filed with letter dated

19 December 2012, or one of the seventh and eighth auxiliary requests, filed with letter dated 28 February 2012.

VII. The respondent requested that the appeal be dismissed.

Its objections on the ground of lack of inventive step of the subject-matter of claim 1 of the main request were only maintained in view of document D4 and document:

D18: "Komplikationen der Dialysetechnik", page 95, Journal für das Nephrologische Team, 3-1998.

VIII. Claim 1 of the main request reads as follows:

"A method of priming an extracorporeal circuit using a dialysis machine comprising a dialysis liquid preparation system having, a source (10, 11, 12) of water, separate sources (20, 15) of bicarbonate concentrate and sodium chloride concentrate, said extracorporeal circuit comprises an arterial line (80), connectable to a patient, for drawing blood from the patient, a venous line (70), connectable to the patient, for returning the blood to the patient, and a blood side compartment (51) of a dialyser, said method comprising the steps of:
- preparing a saline solution from said source (10, 11, 12) of water and said source (15) of sodium chloride to obtain a saline liquid/solution, wherein bicarbonate is absent from the saline solution,
- connecting said arterial line (80) to an outlet of the dialysis liquid preparation system of the dialysis machine and,
- filling the extracorporeal circuit with said saline liquid/solution."

Claims 2 to 12 are dependent claims.

IX. The appellant's arguments relevant to the present decision are summarised as follows:

a) Added subject-matter

The amendment made to the main request to state that bicarbonate was absent from the saline solution was based on page 2, lines 29 to 31 and page 6, lines 27 to 31 of the application as filed. These passages disclosed an embodiment according to which pump 22 (figure 1) was not operated, but pumps 16 and 28 were.

b) Exception to patentability

The respondent raised an objection under Article 53(c) EPC to claim 12 of the main request, which corresponded to claim 12 of the patent as granted, for the first time in its reply to the statement of grounds of appeal. This objection could only be admitted into the proceedings with the appellant's consent, which was not granted.

c) Lack of novelty

D4 related to a haemofiltration machine with a dialysis liquid preparation system including a cartridge of sodium bicarbonate and a cartridge of sodium chloride.

According to a first embodiment as disclosed in paragraph [0034] the machine was primed with a pre-infusion solution including sodium chloride

and sodium bicarbonate prepared from respective concentrates. It followed that this first embodiment was not novelty-destroying for the subject-matter of claim 1 of the main request.

According to a second embodiment, disclosed in paragraphs [0041] and [0042], the dialysis liquid preparation system could be modified such that the priming solution did not contain any bicarbonate. However, paragraph [0041] further explained that the priming solution could be prepared from a single concentrated liquid solution. That implied doing away with the source of bicarbonate concentrate. In that case, the machine provided bicarbonate in a post-infusion solution from a bag with a liquid source of bicarbonate in a ready-to-use concentration (i.e. not concentrated). During treatment, the flow rate of the post-infusion solution had to be lower than that of the substitution solution, as the post-infusion solution was directly injected into the patient. It followed that the second embodiment did not disclose a dialysis liquid preparation system with a source of bicarbonate concentrate, as required by claim 1 of the main request.

Hence, D4 did not deprive the subject-matter of claim 1 of the main request of novelty.

d) Lack of inventive step

The respondent had argued on the basis of D4 and D18.

D18, however, had only been filed more than two years after the filing of the opposition, i.e.

well beyond the opposition period. Moreover it did not disclose any information that was not already in the proceedings, e.g. paragraph [0006] of the patent in suit, which referred to the state of the art. Hence, D18 should not be admitted into the proceedings.

Considering the first embodiment of D4 the closest prior art, the differentiating feature of claim 1 of the main request was the absence of bicarbonate in the priming solution.

Even if D18 taught the exclusion of bicarbonate from the priming solution, the skilled person would simply turn to the second embodiment of D4 and provide the bicarbonate as a liquid, non-concentrated solution in a post-infusion bag. There was no reason to keep a further source of bicarbonate concentrate as required in claim 1 of the main request. According to D4 (paragraph [0011]), employing ready-to-use solutions had a negative impact on the price of the treatment if they were used as a substitution liquid, since large amounts of such a liquid were needed in the treatment. That was not the case for the post-infusion liquid. The subject-matter of claim 1 originated from the idea of using the same dialysis liquid preparation system in two modes, one to provide a priming solution devoid of bicarbonate, and one to provide a dialysis solution with bicarbonate. Such an idea was not hinted at by the prior art and was a novel and inventive advance.

e) No inconsistency was present between column 3, lines 29 to 37 of the description of the patent

and claim 1 of the main request.

X. The respondent's arguments can be summarised as follows:

a) Added subject-matter

The application as filed (page 5, line 30 to page 6, line 2) disclosed that, in order to obtain a saline solution devoid of bicarbonate, pumps 22 and 28 of the dialysis machine were not operated. This had the consequence that none of the salts present in container 26 were present in the saline solution either. However, claim 1 did not specify that pump 28 was stopped, hence it did not exclude the presence in the saline solution of the salts stored in container 26. It followed that the subject-matter of claim 1 was not originally disclosed in its full breadth.

b) Exception to patentability

The subject-matter of claim 12 referred to a situation after priming, in which the treatment of a patient had already begun. Hence, it sought protection for a method of treatment which was not patentable under Article 53(c) EPC.

c) Lack of novelty

D4 was novelty-destroying for the subject-matter of claim 1 of the main request. In particular, it disclosed a priming solution devoid of bicarbonate in paragraphs [0040] and [0041]. In that case it was stated that the priming solution could be prepared from a single concentrated liquid

solution. However, the presence of two concentrated liquid solutions in the dialysis preparation system of the dialysis machine of D4, i.e. also bicarbonate concentrate, was not excluded. Moreover, the solution contained in post-infusion bag 51 could also be considered a concentrate. Claim 1 did not define what a concentrate is. In paragraph [0036] an example was disclosed in which the flow rate of the blood in the machine (300 ml/min) was much higher than the flow rate of the post-infusion solution containing bicarbonate (6.4 ml/min). That hinted at the presence of a concentrate in post-infusion bag 51.

d) *Lack of inventive step*

D18 had been filed as a reaction to the appellant's arguments already in the proceedings at first instance and was relevant as it disclosed that the presence of bicarbonate was undesirable in a priming solution for a dialysis machine. It should be admitted.

The closest prior art was D4, more precisely the first embodiment, which explicitly disclosed a dialysis liquid preparation system including sodium chloride concentrate and sodium bicarbonate concentrate.

The skilled person would use such a system for preparing a priming solution devoid of bicarbonate, since D18 explicitly taught that bicarbonate in a priming solution of a dialysis machine was undesirable and that the priming had rather to be done with a saline solution (right column, second paragraph). Such a preparation did

not involve any technical difficulty, since D4 taught that all its pumps could be adjusted to provide any desired flow rates, e.g. 0. Moreover, the skilled person would have an incentive not to employ a bag with a ready-to-use solution, since D4 taught that such bags were expensive (paragraph [0011]). It followed that the subject-matter of claim 1 of the main request would be arrived at in an obvious way.

e) The definition of the term "saline solution" in column 3, lines 29 to 37 of the description of the patent was inconsistent with claim 1 of the main request. Hence the description could not be left unamended.

Reasons for the Decision

1. The appeal is admissible.

2. The invention

The invention is in the field of extracorporeal blood treatments. More particularly, it concerns a method of priming an extracorporeal circuit for blood using a dialysis machine.

According to the patent in suit, the term "dialysis" encompasses "haemodialysis, haemofiltration, haemodiafiltration, and therapeutic plasma exchange (TPE) among other similar treatments" (paragraph [0020]). Albeit different in their mode of operation, all these treatments aim to replace the renal function of patients who have lost it, eliminating water and metabolic waste products as well

as regulating the concentration of ionic substances and the pH of the blood.

While these treatments are being performed, the patient's blood is drawn out by means of an arterial line and made to circulate in an extracorporeal circuit. The treated blood is re-introduced into the patient by means of a venous line.

The invention focuses on a particular method of priming the extracorporeal circuit, including the arterial and the venous lines, with a priming solution, before the circuit is connected to the patient's body. Such a priming is necessary in order not to inject air or other harmful fluids, possibly already present in the extracorporeal circuit, into the patient's body.

According to the patent, in the prior art such priming was conventionally done using a bag of physiological saline solution. With more modern dialysis equipment capable of performing on-line treatments, i.e. treatments involving the on-line preparation of a substitution fluid used to treat the blood, the priming could be done using the substitution fluid. That would be handier and reduce the costs of the treatment, since no separate source of priming fluid would be necessary (paragraphs [0003] to [0005]).

The fact that the substitution fluid had to contain bicarbonate to provide an effective treatment was, however, a problem, since it had been recorded that infusion of bicarbonate was not well tolerated by some patients (paragraph [0006]).

According to claim 1 of the main request, the invention addresses these problems by providing a priming method

involving the preparation of a saline solution using a dialysis machine without a separate source of priming fluid, wherein the saline solution does not contain bicarbonate. The saline solution is prepared from a source of water and a source of sodium chloride concentrate of a dialysis liquid preparation system of the dialysis machine.

3. *Main request - Article 123(2) and (3) EPC*

Claim 1 of the main request is based on claim 1 and page 5, line 30 to page 6, line 2 of the original application as published, disclosing that bicarbonate is absent from the saline solution used for priming.

The Board agrees with the respondent that this latter passage discloses a mode of operation of the dialysis machine where the operation of pump 28 is stopped, which leads to a saline solution devoid of further additional salts. However, this is only one of the disclosed embodiments. As argued by the appellant, the passages on page 2, lines 29 to 31 and page 6, lines 27 to 31 also disclose an embodiment according to which pump 28 continues to be operated. Thus, there is no need to limit the subject-matter of claim 1 by defining that pump 28 is not operated, and there is a basis for a saline solution without bicarbonate but with further additional salts as well.

Hence, the Board concludes that a limitation of claim 1 to a saline solution without any further additional salts is not required.

The dependent claims are based on respective dependent claims of the application as filed.

It follows that Article 123(2) EPC is complied with.

Since the additional feature concerning the absence of bicarbonate in the saline solution used for priming limits the scope of claim 1 as granted, Article 123(3) EPC is complied with, too.

4. *Main request - Article 53(c) EPC*

As the appellant pointed out, no objection under Article 53(c) EPC was raised within the opposition period as a ground for opposition according to Article 100(a) EPC against granted claim 12.

Since claim 12 of the main request corresponds to claim 12 of the patent as granted, this objection raised by the respondent for the first time in the reply to the statement of grounds of appeal constitutes a fresh ground for opposition.

According to opinion G 10/91 (point 18 of the Reasons), in appeal proceedings fresh grounds for opposition may be considered only with the consent of the patentee.

In the present case the patentee/appellant has not given its consent.

Hence, the Board is not entitled to consider the respondent's objection under Article 53(c) EPC.

5. *Main request - novelty*

In the impugned decision, the Opposition Division held that the subject-matter of claim 1 of the present main request was not novel over D4. The respondent only raised a novelty objection based on D4. The Board, too,

does not see any more relevant documents among the cited prior art and will only consider novelty over D4.

D4 concerns a haemofiltration device. As the Opposition Division correctly pointed out on page 4, fourth paragraph of the impugned decision, in the light of paragraph [0020] of the patent, such a device falls within the general meaning of "dialysis machine" according to claim 1.

More particularly, with reference to figure 1, D4 discloses a haemofiltration machine having an extracorporeal circuit for the blood of a patient, the extracorporeal circuit having an arterial line (5), a venous line (7) and a blood side compartment (2) of a "dialyser". The haemofiltration machine also comprises means for preparing a first solution to be injected into the arterial line (from generator 20, through filters 34 and 38) and means for injecting a second solution into the venous line (from infusion bag 51).

One of the objectives of the invention described in D4 is to perform a haemofiltration treatment with a suitable substitution fluid, i.e. the first solution mentioned above, having high stability (paragraph [0012]). According to D4, in a haemofiltration treatment the patient's blood should be provided with bicarbonate, calcium and magnesium (paragraph [0010]). However, the simultaneous presence in a solution of bicarbonate on the one hand, and calcium and magnesium on the other renders this solution unstable, since magnesium and calcium carbonates are formed and precipitate (paragraph [0007]). It is in order to avoid this problem that D4 proposes keeping bicarbonate separated from calcium and magnesium. More particularly, it teaches that these components should

be provided in one or the other of the first and second injectable solutions, but not in the same one (paragraph [0018]).

In paragraphs [0034] and [0035], D4 discloses a method of priming the extracorporeal circuit of its haemofiltration machine. In this **first embodiment** the generator of the first solution comprises a source of water, a source of sodium chloride concentrate (cartridge 26 in figure 1) and a source of bicarbonate concentrate (cartridge 25 in figure 1), as required by claim 1 of the main request. In this embodiment, the first solution does not contain calcium or magnesium, which are present in the second solution injected into the venous line. The first solution is used to prime the extracorporeal circuit (page 5, lines 43 to 46). **However, this solution contains bicarbonate** (page 5, lines 35 to 37).

It follows that the first embodiment disclosed in paragraphs [0034] and [0035] does not deprive the subject-matter of claim 1 of novelty.

As the respondent pointed out, D4 also discloses that the first solution may not contain bicarbonate, the latter being only present in the second solution. In this case it is the first solution which contains calcium and magnesium (paragraph [0041]).

This disclosure relates to a **second embodiment** of the haemofiltration device. However, while according to this embodiment the priming of the extracorporeal circuit is made with a saline solution devoid of bicarbonate, generator 20 does not contain any source of bicarbonate concentrate (paragraphs [0041] and [0042]). Bicarbonate is provided in the second solution

to be injected into the venous line, i.e. in infusion bag 51, already appropriately diluted. Hence, the "dialyser" of D4 according to the second embodiment **does not contain any source of bicarbonate *concentrate*.**

The respondent's argument that in the second embodiment the absence of bicarbonate concentrate in generator 20 was merely optional is not convincing.

Paragraph [0041] of D4 explains that, if the priming solution does not contain bicarbonate, it can be prepared from a single concentrated liquid solution. In view of the general teaching of D4 to keep magnesium and calcium separate from bicarbonate, this can only mean, in context, that, contrary to the first embodiment, there is no technical reason to have bicarbonate concentrate in generator 20. Consequently, the skilled person understands that generator 20 of the second embodiment only comprises sodium chloride as a source of a concentrated liquid solution. This is also implied in paragraph [0041], second sentence, in which it is expressly stated that the apparatus comprises means for diluting a single concentrated liquid solution.

With regard to the respondent's argument that post-infusion bag 51 includes a liquid concentrate, the Board is of the opinion that the term "concentrate" implies a liquid which cannot be injected as it is, but requires a previous dilution. D4 does not foresee any means for diluting the content of bag 51. The argument that the relatively low flow rate of the post-infusion solution containing bicarbonate may hint at the presence of a concentrate in post-infusion bag 51 is not convincing either. The relatively low flow rate from post-infusion bag 51 compared to the flow rate of

the substitution fluid simply derives from the working principle of a haemodialysis machine, in which the substitution fluid, to a large extent, is circulated through an ultrafiltration membrane, whereas the post-infusion solution is directly injected into the patient.

It follows that the second embodiment does not deprive the subject-matter of claim 1 of novelty either.

Hence, the subject-matter of claim 1 is novel (Article 54 EPC).

6. *Main request - inventive step*

At the oral proceedings, the respondent only maintained an objection as to lack of inventive step based on D4 and D18. The appellant objected to the admissibility of D18.

The Board considers the late filing of D18 as a fair and justified response to the amendment in the main request compared to the patent as granted. More particularly, D18 addresses advantages of not having bicarbonate in the saline solution used for filling the extracorporeal circuit of a dialysis machine, which is exactly what is specified by that amendment. Its disclosure is more detailed than the brief mention of some of these advantages in the discussion of the prior art in the patent in suit. Hence, in exercising the discretion conferred to it by Article 114(2) EPC, the Board decides to admit D18 into the proceedings.

The respondent considered the first embodiment of D4 as the closest prior art.

The Board notes that this embodiment relates to a method of priming an extracorporeal circuit of a dialysis machine of the kind defined in claim 1. Moreover, as shown above, the subject-matter of claim 1 differs from this known method only in the saline solution used for filling the extracorporeal circuit, i.e. only one technical feature.

For these reasons the Board agrees with the respondent that the first embodiment of D4 can be considered as the closest prior art.

The subject-matter of claim 1 differs from the closest prior art in that the saline solution used for filling the extracorporeal circuit does not contain bicarbonate.

The technical effect of this difference is that, once the dialysis treatment is started and the saline solution is directly injected into the patient, the latter does not receive bicarbonate.

As derivable from paragraph [0006] of the patent in suit, since the infusion of priming liquid containing bicarbonate into a patient may cause problems, i.e. feeling unwell, the objective technical problem to be solved by the invention is to improve the patient's comfort during a dialysis procedure.

D18 teaches that injecting a priming solution containing bicarbonate into a patient may create several problems. Hence, as the respondent submitted, it hints at performing the priming with a saline solution devoid of any bicarbonate. However, no further details about a specific priming method are provided.

As the appellant argued, D4 already teaches how to fill the extracorporeal circuit of its dialysis machine with a saline solution without bicarbonate if desired, i.e. according to the second embodiment in which bicarbonate is only present in a post-infusion bag. On the contrary, using generator 20 of the first embodiment for generating a priming solution without bicarbonate and, subsequently, for generating a substitution solution with bicarbonate is simply not taught in the available prior art.

The respondent's argument that the skilled person would have an incentive not to employ bags with a ready-to-use solution is likewise not convincing. D4 teaches that such bags may increase the price of treatment if used to deliver the substitution fluid (paragraph [0011]), of which large quantities are needed. It does not teach against employing them to provide post-infusion solutions. Quite on the contrary, it expressly discloses it in its second embodiment.

In view of the above, the Board concludes that the subject-matter of claim 1 of the main request involves an inventive step, too (Article 56 EPC).

7. *Main request - support by the description*

The fact that it is stated in column 3, lines 29 to 37 of the description of the patent that the term "saline solution" covers solutions containing minor amounts of other electrolytes such as potassium, calcium, magnesium, glucose and/or acid is not in contradiction with the requirement in claim 1 that bicarbonate is absent from the saline solution. Accordingly, claim 1 is supported by the description in compliance with Article 84 EPC.

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:

   - claims 1 to 12 of the main request filed with letter dated 28 February 2012; and

   - the description and figure 1 of the patent as granted.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated