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**Datasheet for the decision
of 29 July 2009**

Case Number: T 0794/06 - 3.2.02

Application Number: 95114362.7

Publication Number: 0714668

IPC: A61M 1/14

Language of the proceedings: EN

Title of invention:

Method and arrangement for centrally preparing a salt concentrate, a method for disinfecting the arrangement and the use of a container in the arrangement

Patentee:

Gambro Lundia AB

Opponent:

Fresenius Medical Care Deutschland GmbH

Headword:

-

Relevant legal provisions:

EPC Art. 53(c)

Relevant legal provisions (EPC 1973):

EPC Art. 123, 84, 52, 54, 56

Keyword:

"Extension of subject-matter (no)"
"Method of treatment by therapy (no)"
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:

-

Catchword:

-



Case Number: T 0794/06 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 29 July 2009

Appellant: Fresenius Medical Care Deutschland GmbH
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
23 March 2006 concerning maintenance of
European patent No. 0714668 in amended form.

Composition of the Board:

Chairman: S. Chowdhury
Members: P. L. P. Weber
M. J. Vogel

Summary of Facts and Submissions

I. The Appeal is against the interlocutory decision of the opposition division posted on 23 March 2006 that account being taken of the amendments according to the main request made by the proprietor during the opposition procedure, the patent and the invention to which it relates meet the requirements of the EPC.

II. The notice of appeal was filed by the opponent (appellant) on 18 May 2006 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 28 July 2006.

III. The following documents played a role in the appeal proceedings :

D2 : DE-T2-69004739 (German family member of D1 : EP-A-0401130)

D3 : EP-A-0613688

D4 : EP-A-0278100

D8 : EP-A-0208090

D9 : EP-A-0458041

IV. Oral proceedings took place on 29 July 2009.

The appellant requests that the decision be set aside and the patent be revoked.

The respondent (patentee) requests that the decision under appeal be set aside and the patent be maintained on the basis of claims 1 to 4 as maintained by the opposition division and claim 5 as filed on 26 June

2009, the description as maintained by the opposition division and the drawings as granted.

V. Claim 1 reads as follows:

"1.1 Method for centrally preparing on line and distributing on line a concentrate of only one salt in water for preparation of a medical solution starting from the concentrate, especially dialysis solution and/or replacement solution for haemodialysis, haemofiltration or haemodiafiltration, comprising :

1.2 supplying primarily water to a water tank and

1.3 supplying said water to a container containing the salt in particle form, in a quantity of at least 10 kg,

1.4 removing substantially saturated concentrate of the salt in water from the container,

1.5 distributing the substantially saturated concentrate to a distribution conduit and substantially saturated concentrate connectors arranged thereon, for preparation of the medical solution."

Claim 5 reads as follows:

"Method for disinfecting an arrangement intended for central preparation and distribution of a concentrate of only one salt in water for preparation of a medical solution starting from the concentrate, especially dialysis solution and/or replacement solution for haemodialysis, haemofiltration or haemodiafiltration, comprising

a concentrate generator (1) provided with an inlet (4) for water and at least one distribution conduit (6) for distribution of the concentrate to concentrate-connectors arranged thereon (8),

at least one container (2, 3) for said salt which is at least partially in solid form, the container being adapted to contain the salt in a quantity of at least 10 kg;

a conduit (10) for supplying primarily water to the container (2, 3) to form a substantially saturated concentrate of the salt in water in the container (2, 3) by partial dissolving of the salt in the water; and

a conduit (11) for feeding the concentrate to the distribution conduit (6) and concentrate connectors arranged thereon,

characterized in that

the concentrate is recirculated in a recirculation circuit comprising at least the distribution conduit (6), and in that

the concentrate is heated to a temperature above 90°C, and possibly at an overpressure, to attain disinfection of the recirculation circuit."

Claims 2 to 4 are dependent claims.

VI. The arguments of the appellant can be summarised as follows:

Formal aspects

"on line"

The word "on line" could be interpreted in several ways: to specify that the device was connected with a central water supply system, that the device was connected with one or more patients, that the preparation of the concentrate was done at the same time as the supply of water, or that the preparation was done at the same time as it was used or that the preparation was done continuously. Because it was not clear which one of the meanings was meant claim 1 was not clear.

In addition the term "preparing on line" as well as the term "distributing on line" were not disclosed in the originally filed application. As a matter of fact the term "on line" could only be found in connection with the preparation of a concentrate with common salt and whereby the salt was dissolved during use.

"substantially saturated"

This term was not clear as it was not clear what kind of deviations from the saturation the concentrates could have and still fall under the claim.

It was also not clear what exactly "substantially saturated concentrate connector" was.

Further, amendment by way of introducing the term "substantially saturated" contravened Rule 80 EPC because it was not occasioned by a ground of opposition.

Method of treatment

The word "on line" in claim 1 meant that a patient must be connected to the device. Since according to paragraph [0076] of the patent in suit the concentration of salt could vary, this variation in the concentration would also have an effect on the patient which meant that it would have an effect on the therapy applied to the patient. This method of preparing a concentrate on line had therefore to be considered a method of treatment by therapy excluded from patentability by Article 53(c) EPC.

In this connection it was particularly important to note that the claim required the distribution of the concentrate once prepared. Even if this was only a part of a method for therapy it had to be excluded from patentability.

The second sentence of Article 53(c) EPC possibly allowed the patentability of pharmaceutical compositions but the present claim was not claiming a pharmaceutical composition but a method of preparation and distribution of a medical solution, and the patient was connected and treated while connected. Without a patient the method was not executed. There was thus a clear interaction between the method and the patient.

Inventive step

Document D3 disclosed the central distribution of concentrate as could be seen for instance in Figure 6. A distribution conduit was shown to which several dialysis machines could be connected. It was also disclosed that the basic concentrate could be obtained

by mixing an amount of dry substances with water and further it was disclosed on page 5 that it was known to use a basic concentrate with only one salt.

Given the number of dialysis machines connected, the quantity of salt necessary in the system of D3 also had to be higher than the 10 kg claimed in claim 1. Further it was self evident that the concentrate would be taken from the conduit.

It was also disclosed in D3 that the basic concentrate could be introduced into the distribution conduit without being diluted, see page 15. In view of the above, the subject-matter of claim 1 had to be considered anticipated. If a difference could be seen in the use of a saturated salt concentrate, the use of a saturated salt concentrate in such a system was suggested in document D2, so that the subject-matter of claim 1 was in any case not inventive.

The subject-matter of claim 1 was also not inventive starting from the prior art cited in D3 on page 6 as the claimed subject-matter differed only in an alternative way of centrally preparing the concentrate, which alternative way was suggested in D2.

The subject-matter of claim 5 was not inventive as document D3 mentioned the hygienic qualities of a salt concentrate and documents D8 or D9 suggested the recirculation of the fluid for disinfection purposes.

VII. The arguments of the respondent can be summarised as follows:

A method for centrally preparing on line and distributing on line concentrate of only one salt in

water for preparation of a medical solution was originally disclosed and gave the skilled man a clear teaching. For instance in column 7 it was mentioned that the common salt was dissolved on line according to the requirements, it was also stated that the common salt was dissolved during use, so that not only was it clear what was meant by the words "on line" but this wording was also originally disclosed.

The term "substantially saturated" was introduced in features 14 and 15 to make it clear that any deliberate dilution of the concentrate after removal from the container and before distribution into a conduit was no longer covered by claim 1. Paragraph [0014] of the patent in suit had been cancelled accordingly.

Paragraph [0076] of the patent gave a definition of the saturated concentrate.

The addition of this term in relation to the connector was only to state that the connector was for the substantially saturated concentrate.

Method of treatment

The claimed method could not be considered to be a method of treatment because if a concentrate saturated in salt entered the patient he would be dead within 3 minutes. In addition the concentrate had to be considered to be a composition within the meaning of the 2nd sentence of article 53 EPC. For such compositions it was possible to grant patents.

The method related to the central preparation of a saturated concentrate and not to the preparation of a

medical solution. The claimed method stopped at the connectors.

Inventive step

In document D3 the basic concentrate could be prepared batchwise or continuously but there was no mention that the basic concentrate was prepared on line. When it was prepared continuously water was supplied to a container in which the dissolution of the salt took place. Thus already the feature that the water was supplied to a water tank was missing in D3. In addition the water was not supplied to a container containing the salt but the salt was introduced into the container filled with water. Furthermore D3 disclosed neither the preparation of a substantially saturated concentrate nor the preparation of a concentrate of only one salt. Instead, it disclosed the preparation of a basic concentrate of a mixture of 2 salts which also implied that the concentration of each of the salts in the concentrate had to be monitored and regulated. D3 did not disclose preparing a substantially saturated concentrate, so it could not distribute such a concentrate either.

Document D2, at least did not disclose the distribution of a saturated concentrate, so it could not suggest the subject-matter of claim 1. It should be noted in this context that document D2 was public when the invention according to document D3 was made, but the inventor choose not to go the same way.

For this reason claim 1 was not only new but also based on an inventive step.

The fluid which was recirculated in the device according to document D8 or D9 was the sterilising fluid and not a component of the dialysis fluid so that this document could not suggest the subject-matter of claim 5.

Reasons for the Decision

1. The appeal is admissible.

Claim 1

2. Article 123(2) EPC and Article 84 EPC

According to the appellant the terms "preparing on line" and "distributing on line" added during the opposition procedure were originally not disclosed. The same was true for the terms "substantially saturated concentrate" as well as "substantially saturated concentrate connectors".

Apart from not being originally disclosed these terms were also not considered clear by the appellant.

"on line"

The word "on line" is used in the paragraphs going from col. 4, line 58 to col. 5, line 24 of the A1 publication of the application. In the Board's opinion it means none other than the fact that the concentrate is prepared and distributed when there is a need on the patient side (or on the dialysis machine side), in other words when the patient is "on line". This is the teaching of the whole patent as opposed to a method of

preparation which consists of preparing batchwise a quantity of concentrate and then using it until none is left, preparing some concentrate again, and so on.

The appellant argued that the word "on line" was only used in connection with the preparation of a common salt concentrate so that it should be specified in the claim that a concentrate with common salt is prepared on line.

The Board cannot share this opinion as the originally filed claims were about preparation of a concentrate of substantially only one salt in general and not limited to common salt, and in the originally filed description it was mentioned that other salts than common salt could be prepared centrally according to the invention (see column 7, lines 55, 56).

"substantially saturated"

It is clear already from the Figures, see Figure 2, that the same liquid as the one removed from the container enters into the distribution line. It is stated for example in col. 2, lines 37 to 40 that the dialysis machine must be provided with an inlet for substantially saturated NaCl solution, and in col. 5, lines 52, 53 that the water in the container is substantially saturated with dissolved common salt. Moreover at numerous places in the description it is stated that a saturated solution leaves the salt container. For consistency the same terminology is used in feature 1.5 as in feature 1.4 of claim 1. The paragraph [0076] of the patent makes it clear that accidental "non saturated" situations may occur but in

the Board's view this only confirms that the intention is to have a saturated concentrate. In fact this paragraph gives the definition of the term "substantially saturated". It is to be noted in this context that the mentioned deviations are not due to intentional mixing with water.

In addition the paragraphs which might have cast doubt on the scope of claim 1 (see [0014], [0073]) have been deleted from the specification documents to be maintained.

The word "substantially" was also used in the originally filed description, moreover, it is the most common adverb used in the English patent world for covering slight deviations. For these reasons the use of this term is both allowable under Article 123(2) EPC and also clear.

3. In the opinion of the Board it can also not be said that the amendment consisting of the introduction of the term "substantially saturated" is unallowable under Rule 80 EPC.

During the opposition proceedings the respondent wanted to limit its patent to the case in which a saturated concentrate was prepared as opposed to the granted claim which covered both the preparation of a saturated concentrate and of a non-saturated concentrate. It is therefore in line with this intention to specify wherever necessary in the claim that by concentrate is meant substantially saturated concentrate, in order to avoid possible novelty attacks based on documents disclosing concentrates which are not saturated.

4. Method of treatment

The appellant considered the claimed method to be a method of treatment by therapy since the method was executed while the patient was on line and because it necessarily had an influence on the patient's treatment when the concentration in salt varied in the concentrate as explained in paragraph [0076].

The Board cannot agree with this argument.

The claimed method is a method for centrally preparing on line and distributing on line a substantially saturated concentrate of only one salt to a distribution conduit and to connectors for preparation of a medical solution.

It is apparent from the wording of the claim that the prepared concentrate which is available at the connectors is for the preparation of a medical solution and is not the medical solution itself, and this concentrate thus does not reach the patient's blood. The method thus only is for preparation of a component of that medical solution.

It is further apparent from the wording of the claim that any step performed after the concentrate leaves the connectors is not part of the claimed method.

It is additionally to be noted in this context that the appellant did not name any substantially saturated concentrate of only one salt which might be usable per se as a medical solution for therapeutic treatment.

In the case of the preparation of a substantially saturated concentrate in salt for preparation of a dialysis solution and/or replacement solution for haemodialysis, haemofiltration or haemodiafiltration, as is particularly mentioned in the claim and as is described as a specific embodiment of the invention in the description of the patent in suit, it is to be noted that the saturated salt concentrate could not be used as such in one of the mentioned methods of treatment without killing the patient.

In the case of the use of the concentrate in these methods the dialysis machine will be connected to the connectors and it is the dialysis machine which will open or close the fluid connection to the distribution conduit. Once in the dialysis machine the substantially saturated concentrate must be rendered usable by the addition of other substances to prepare the final medical solution adapted to the needs of the patient. This preparation of the medical solution and adaptation to the patient's needs starting with the saturated concentrate will occur within the dialysis machine. Even though the patient is on line the step of preparation of this saturated component entering the dialysis machine as a "basic component" cannot be considered to be part of the method of treatment by therapy. The therapy comprises the circulation of the solution adapted to the needs of the patient for a particular time which is also adapted to the needs of the patient. The preparation of a basic component of such a medical solution has no bearing whatsoever on the final composition of the solution adapted to the patient or on the length of the treatment applied to a particular patient. There is thus no interaction

whatsoever between the patient and the saturated concentrate.

The claimed method thus cannot be considered to fall within the concept of a method of treatment by therapy excluded from patentability pursuant to Article 53(c) EPC.

In the Board's opinion the presently claimed method is no more than a method for preparing a component of a medical solution, the method having some technical and hygienic advantages.

5. Novelty

Documents D2, D3 and D4 were cited in relation with novelty and inventive step.

5.1 In D3 it is disclosed that on line distribution (but not preparation) from a centrally located source of standardised concentrate is known, see for instance page 6, lines 10 to 14.

The difficulty with this kind of distribution line is seen in the fact that the composition of the concentrate must have an average concentration of substances suitable for most of the patients but it cannot be specifically adapted to a given patient's needs. Additionally heavy concentrate quantities have to be stored and transported.

To solve this problem D3 proposes the preparation in two steps, a standardised "basic concentrate" is provided on line in a first step and an "individual concentrate" is distributed to each of the dialysis

machines in a second step so that the final solution can be adapted to the patient's needs.

The "basic concentrate" is a mixture of sodiumchloride and sodiumbicarbonate (see page 6, line 53 to page 7, line 6) and it can be provided in several forms, see page 6, lines 10 to 19.

In the embodiment according to Figure 6 a ready to use "basic concentrate" is distributed, see page 14, lines 32 to 35. In the embodiment according to Figures 7 and 8 the "basic concentrate" is obtained by feeding pellets, tablets (Fig.7) or powder ground from a solid piece (Fig.8) of salt mixture into a reservoir 103 filled with water. These two embodiments have the advantage that the salt mixture can be provided in solid and dry form.

In the Board's opinion only the embodiments according to Figures 7 and 8 can be considered to include centralised preparation as required by feature 1.1 of claim 1. However the mixture or concentrate prepared contains two salts and not just one as required by feature 1.1.

A water tank which stores water before it is fed to a mixing tank as required by feature 1.2 is also absent in the device according to D3.

A container containing the salt in particle form (moreover in a quantity of at least 10 kg) into which water is supplied as required by feature 1.3 is also absent in the device according to D3.

On page 17, lines 4, 5 of D3 it is indicated that the accumulation of undissolved salts should be avoided, which implies that an excess of water must be present, and thus the water leaving the system is not saturated with salt.

It is also mentioned on page 12, lines 41 to 48 in connection with one of the examples that the concentration of sodium in the "basic concentrate" should not be too high, so as to be able to adapt the concentration to the patient's needs. More specifically it is mentioned that the salt concentrate should be slightly lower than the one needed by the patient so that the concentration of salt can be adapted to the individual needs of the patient by addition of the individual concentrate provided at each dialysis machine. This implies that the concentration of salt in the solution fed into the distribution line is far from saturated.

The concentrate which is removed from the mixing container is thus not saturated as required by feature 1.4.

The appellant considers that document D3 discloses the use of a basic concentrate of only one salt.

The passage on page 5 mentioned by the appellant concerns a state-of-the-art bicarbonate dialysis method. It is mentioned in the context of such a dialysis method that it is common to provide a concentrate of sodium-bicarbonate together with the 2nd concentrate of the remaining elements of the dialysis fluid. This has no bearing on the method described in relation with

Figures 7 and 8 showing embodiments of the invention according to document D3.

In connection with the embodiments of the invention according to D3 it is to be noted that it is mentioned on page 7, lines 10 to 13 that the "basic concentrate" could be provided in the form of two liquid concentrates, one with only sodiumchloride and one with sodiumbicarbonate. There is however no embodiment disclosed in D3 which shows how the whole system should be conceived in such a case. In any case the "basic concentrate" which is fed to the distribution line is a two-salt concentrate and, as mentioned above, document D3 does not teach the use of saturated concentrates.

5.2 D4 discloses an arrangement for preparing a dialysis solution on line when the patient is connected or shortly before (see page 4, lines 9 to 11, page 5, lines 11 to 15). Water flows through a container containing a concentrate in powder form. The substantially saturated liquid (see page 6, lines 23 to 27) coming out of the container flows through a flow regulating device and is mixed with water to obtain the desired concentration for the patient. The size of the salt containers is mentioned on page 11, lines 33 to 43 (appr.1,500 kg). This arrangement is thus not for preparing a concentrate centrally and distributing it over a distribution line to several dialysis machines.

5.3 D2 discloses an on line system for preparing a concentrate for dialysis. The beginning of the description in D2 refers to D4 and to the problems with the device according to D4 which are said to be solved

by the device according to D2. Since D4 discloses a single treatment device a central preparation system was not contemplated in D2 either.

In addition in the device according to D2 the concentrate is diluted before it is sent into the distribution line, see col. 4, lines 4 to 10, col. 6, lines 5 to 17.

The size of the salt container is not explicitly mentioned in D2, but it must be assumed that it is for one treatment only as in the device according to D4.

5.4 None of the cited documents is thus novelty destroying for the subject-matter of claim 1. The subject-matter of claim 1 is thus novel.

6. Inventive step

6.1 Document D3 discloses a method of distributing a basic concentrate on line, and the Board considers this document to disclose the closest prior art. More particularly the embodiments according to Figures 7 and 8 are considered to constitute the closest prior art because in these embodiments the basic concentrate is prepared starting with salts in dry form.

The appellant considered that the prior art according to D2 or the one cited in D3 on page 6, lines 10 to 15 could also constitute starting points to arrive in an obvious way to the invention.

The Board cannot agree with this finding as the device and method disclosed in document D2 are not for centrally preparing and distributing a concentrate and

there is no teaching whatsoever concerning this aspect in this document. Concerning the state-of-the-art mentioned in the introductory part of document D3 it is considered that it is further away from the invention than the embodiments according to Figures 7 and 8 as it is specifically mentioned that big tanks of concentrate are used for the concentrate distribution.

- 6.2 Over the method disclosed in D3 the differentiating features can be seen in the on line preparation of a concentrate of only one salt in water, in the supplying of the water to a container containing the salt in particle form in a quantity of at least 10 kg, and in the distribution of substantially saturated concentrate of the salt in water.

These features provide several advantages. As a concentrate of a single salt is prepared and distributed, no specific monitoring and regulating of the concentration of each of the two salts is necessary as in the case of preparing the basic concentrate of D3. As a saturated concentrate is prepared by filling a container containing salt in particle form with water, rather than filling a container containing water with salt (as in D3), precise monitoring and regulating of the quantity of salt introduced in the water is avoided. The provision of salt in dry form avoids the transportation of big and heavy containers. Finally at least in the case of the preparation of a concentrate of common salt, the same concentrate as the one prepared for the medical solution can be used for sterilisation of the system, thus avoiding change of the fluid in the whole system.

Hence starting from the prior art according to D3 the objective problem can be seen in providing an improved centralised on line distribution of a component for preparation of a medical solution.

6.3 Neither the document D3 itself nor any of the other documents cited in the appeal proceedings suggests the claimed solution.

As explained above the documents D2 and D4 do not relate to a central on line preparation of a concentrate nor do they relate to the on line distribution of such concentrate to several dialysis machines. For this reason alone it is questionable whether the person skilled in the art would have considered these documents.

In any case even if he did so, in addition to not suggesting a central on line preparation for several machines, as explained above, none of these two documents suggests distributing a saturated concentrate in the distribution line.

The appellant argued that if the person skilled in the art wished to improve the preparation of the concentrate disclosed in D3, D2 would lead the person skilled in the art to the claimed solution.

While it is true that according to D2 a first concentrate is prepared by flowing water into a container containing salt in powder form, as explained above, not only is this for one treatment only, there is also no suggestion whatsoever to do the same centrally for several treatments, and also it is

clearly disclosed to distribute the final medical solution after the distribution unit 27. In other words even if the person skilled in the art were to consider D2 for a central preparation system this document teaches to distribute the final medical solution centrally or at least this document does not give any indication whatsoever as to what exactly should or could be prepared centrally and what could be prepared locally with what kind of advantages in each case. In the opinion of the Board the analysis made by the appellant is a typical ex-post facto analysis in which, having knowledge of the invention, one tries to find a way to it by reading a prior art document in a way in which a person skilled in the art not knowing the invention would never do.

Claim 5

7. Novelty and inventive step

The subject-matter of claim 5 is a method for disinfecting an arrangement intended for the central preparation and distribution of a concentrate of only one salt in water for preparation of a medical solution starting from the concentrate, whereby a substantially saturated concentrate is prepared and the same concentrate as the one intended to be distributed is recirculated in a recirculating circuit comprising at least the distribution conduit to perform disinfection.

None of the cited documents specifically addresses the sterilisation of such an arrangement intended for the central preparation and distribution of a concentrate. In document D3, which is concerned with the central

preparation and distribution of a concentrate, there is no specific and complete teaching as to how the sterilisation of this arrangement should be done. The only remark about the sterilisation present in this document is found on page 15, lines 4 to 7, where it is mentioned that the heating unit 9 used for heating the dialysis liquid to the body temperature can also be used to sterilise the conduit before and after use with hot water. This is evidence of the fact that the person skilled in the art who wrote document D3 did not think of a way of sterilising the conduits other than by the classical use of hot water.

There is thus no suggestion of the subject-matter of Claim 5 in this document.

The appellant considers that the person skilled in the art would be guided by document D3 to use the basic concentrate mentioned in this document for sterilisation as explained on page 14 according to which this concentrate has hygienic advantages as it hinders multiplication of microorganisms. In addition document D8 is said to suggest a recirculation of the fluid for sterilisation.

The Board cannot agree with the appellant since the writer of document D3, while having recognised the hygienic advantages of the basic concentrate, nevertheless mentions the use of hot water for sterilisation.

Document D8 mentions the recirculation of a fluid, but the fluid meant is the sterilisation fluid and not a concentrate of one salt used for preparation of the

dialysis fluid, so that this document cannot suggest recirculating the dialysis fluid. The same is true for D9.

The method of claim 5 is therefore novel and inventive.

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 the first instance with the order to maintain the patent in the following version:
 - claims 1-4 as maintained by the opposition division,
 - claim 5 as filed on 26 June 2009,
 - description as maintained by the opposition division,
 - drawings as granted.

The Registrar

The Chairman

D. Sauter

S. Chowdhury