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D E C I S I O N
of 17 December 2002

Case Number: T 0797/00 - 3.2.2

Application Number: 94919325.4

Publication Number: 0652780

IPC: A61M 1/16

Language of the proceedings: EN

Title of invention:
Apparatus for preventing hypotension in a dialysis patient

Patentee:
BAXTER INTERNATIONAL INC.

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (no)"
"Problem-solution approach and relevant prior art documents (point 5)"

Decisions cited:
T 0176/84

Catchword:
-

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Case Number: T 0797/00 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 17 December 2002

Appellant: (Opponent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 26 May 2000 rejecting the opposition filed against European patent No. 0 652 780 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: M. G. Noel
R. T. Menapace

Summary of Facts and Submissions

I. Following an opposition filed by the appellant against European patent No. 0 652 780 (International publication No. WO 94/27 658), the Opposition Division decided on 26 May 2000 to reject the opposition and to maintain the claims as granted, after having considered the state of the art represented, in particular, by documents:

D1: DE-A-3 416 057, and

D2: US-A-4 710 164.

II. The reasons given by the first instance were that the prior art documents led the skilled person to overcome hemodialysis related hypotension by automatically controlling the sodium content of the dialysis fluid. As could be taken from D2, the skilled person even was directed away from any manual control or intervention by the dialysis personnel. Even if the skilled person had made the choice of controlling the sodium concentration of the patient's blood via the hemodialysis machine, he would have been led to a fully automatic control provided by a pre-programmed unit rather than to a manually actuable means as defined in claim 1. Therefore, the prior art taught away from a combination of an automatic control with said manually actuable means, which advantageously allowed the patient itself to initiate sodium delivery to the dialysis liquid whenever he felt unpleasant due to beginning hypotension.

III. The appellant lodged an appeal on 29 July 2000 against the first instance's decision and filed a statement of

grounds on 4 October 2000. The respondent (patentee) replied on 20 April 2001.

IV. In a communication of the Board dated 15 July 2002 sent following a summons to attend oral proceedings, the parties were informed of the preliminary opinion of the Board according to which the subject-matter of claim 1 as it stood appeared to lack an inventive step.

V. The appellant replied on 14 November 2002, filing a new document:

D7: US-A-4 627 839.

The respondent replied in turn on 15 November 2002, filing additional sets of claims according to the first and second auxiliary request.

VI. Oral proceedings were held on 17 December 2002, during which the respondent filed further amended claims according to third and fourth auxiliary request. The discussion was then focused on documents D1, D2 and D7, this latter having been introduced by the Board in the proceedings.

VII. At the end of the oral proceedings, the requests of the parties were as follows:

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

The respondent requested that the appeal be dismissed and that the patent be maintained as granted (main request) or that the decision under appeal be set aside

and that the patent be maintained in amended form either on the basis of the two sets of claims filed with letter dated 15 November 2002 (first and second auxiliary requests) or on the basis of a combination of claims 1 and 10 as granted (third auxiliary request) or of claims 1 and 5 as granted (fourth auxiliary request).

VIII. The parties submitted the following arguments:

(i) The appellant:

It is known from the background of document D2 to prevent patient hypotension during hemodialysis either manually by the dialysis personnel through the direct injection of a bolus of saline into a blood line to the patient or fully automatically by way of the dialysis machine during the treatment. D2 discloses a fully automated apparatus for automatically initiating delivery of sodium to the dialysate in order to increase the sodium concentration upon occurrence of a hypotension episode, in conformity with the precharacterising clause of claim 1. Therefore, the skilled person, from the very beginning had the choice between a manual or a fully automatic intervention. A third intermediate option was to manually set the dialysis machine to a preselected value of the sodium concentration.

Document D7 discloses a programmable infusion apparatus used to administer a medication to a patient without recourse to a nurse, by which the patient can trigger the administration of a predetermined infusion of medication at limited

intervals. According to Figure 5, manually actuable means are remotely connected with control means (microprocessor) for initiating the administration of a dose. Since said manually actuable means are suitable generally for automatically delivering a bolus of fluid in response to a signal that may be generated by the patient or other healthcare personnel, the subject-matter of claim 1 is suggested by the combination of documents D2 and D7.

The features added to the first and second auxiliary request, that the apparatus comprises a housing and that the manually actuable means includes a cable and a button at the distal end thereof, are of trivial nature and also known from document D7. The features added to the third and fourth auxiliary requests, to prevent sodium overdosing upon manual actuation by the patient, are also disclosed by D7, in particular by a dosing button which allows the delivery of doses at pre-selected time intervals.

(ii) The respondent:

Documents D1 and D2 both provide fully automated hemodialysis systems for raising the sodium concentration in the dialysate in order to overcome hypotension problems. In particular, D2 expressly excludes any manual intervention by the dialysis personnel, which clearly leads away from any manual control.

Document D7 relates to a device for administering analgesic medication by the patient itself,

whenever it deems it necessary. Even if the problem of avoiding the burdens on the nurses is generally the same as in the present patent, this document refers to a technical field which is far remote from hemodialysis and patient-controlled delivery of a bolus of saline in the dialysate at the first onset of hypotension. The person skilled in the art, therefore, had no reason to combine the teachings of document D2 and D7, the more since it would not find in D2 any suggestion to do so. A further indication of inventive step is the notable simplicity of the solution, which despite the considerable amount of activity in this field had escaped those concerned.

The claims amended according to the various auxiliary requests specify the means used for generating and transmitting a control signal in response to actuation of the manually actuable means or for avoiding sodium overdosing. These means in combination with the other features, are not disclosed by the cited documents.

IX. The independent claims according to the various requests read as follows:

Main request (version as granted):

"A hemodialysis apparatus comprising a dialysate source, a sodium source, a dialysis membrane connected in fluid communication with each source, and a control means operatively connected with the sodium source for initiating delivery of sodium from the sodium source to the dialysate to increase the sodium concentration in the dialysate at the membrane,

characterised by a manually actuable means (12) connected with the control means, the control means being responsive to a signal generated by manual actuation of said manually actuable means (12) for initiating said delivery of sodium."

First auxiliary request: The content of claim 1 according to the main request and the following additional feature:

"and wherein the apparatus is housed in a housing and the manually actuable means includes a cable (18) extending from the housing and having a button (20) at the distal end thereof, the signal being generated by actuating the button, or a remote control."

Second auxiliary request: the content of claim 1 according to the first auxiliary request, after deleting the last four words "or a remote control".

Third auxiliary request: the content of claim 1 according to the main request and the following additional feature:

"the haemodialysis apparatus including means for restricting sodium delivery to a predetermined number of milliequivalents thereof."

Fourth auxiliary request: the content of claim 1 according to the main request and the following additional feature:

"wherein the control means includes software for controlling the maximum number of deliveries to the dialysate and the delivery interval, to prevent sodium

overdosing."

Reasons for the Decision

1. The appeal is admissible.

2. *Late-filed document*

Document D7 was filed by the appellant in response to the preliminary opinion of the Board considering more favourably at that time some specific features of the dependent claims. Although filed late, document D7 was admitted by the Board into the proceedings under Article 114(1) EPC, by reason of its particular relevance.

3. *Closest state of the art*

Document D2 represents the prior art closest to the invention, because it is functionally similar to the claimed invention. D2 is acknowledged in the background of the patent in suit as disclosing the precharacterising features of claim 1 (all requests), in particular (cf. Figure 1; abstract and column 4, lines 8 to 15) a hemodialysis machine 16 including a circuitry for controlling the addition of a sodium solution from a reservoir to the dialysate to obtain a desired conductivity. The sodium concentration is normally controlled by the machine in the absence of control signals from the microprocessor. The microprocessor is programmed to detect deviation of heart rate and blood pressure from initial readings and to initiate control action accordingly. If, for example, a blood pressure limit is detected as

indicating the onset of a hypotensive episode, therapeutic intervention is immediately initiated by increasing the dialysate sodium concentration for a period of time (3 minutes). If the alarm condition persists, the dialysis monitoring staff is alerted.

Document D2, therefore, provides a fully automated apparatus for continuously monitoring patient vital parameters during hemodialysis and for automatically initiating therapeutic intervention upon occurrence of a hypotensive episode.

4. *Problem and solution (main request)*

In document D2 control means are automatically activated to overcome the drawbacks of the prior completely manually operated injection of sodium into a patient's blood line. A manual intervention requires continuous observation and monitoring of the patient by the dialysis personnel. As mentioned in the patent in suit, the burdens on the nurses are such that they may be prevented from delivering saline to a specific patient at the first onset of symptoms of hypotension. On the other hand, as submitted by the respondent, the fully automatic system proposed in D2 is not satisfactory, because it is dependent on the initial readings of the patient's parameters being correlated to a correct sodium ion concentration in the blood, which is not necessarily correct. Moreover, monitoring of heart rate and blood pressure provides only for an indication of hypotension when the problem already exists. Many patients, therefore, still have to suffer discomfort.

Starting from document D2 according to which both kinds

of intervention, either manually or automatically operated, are generally known to have been in use although both not being totally satisfying, the technical problem underlying the present patent is to provide another alternative to the manual intervention, which enables the sodium concentration of the dialysate to be increased immediately and before the patient drops into an alarming condition, thus avoiding the major drawbacks of both known kinds of intervention.

The solution is given by the characterising features of claim 1, in particular by a manually actuable means connected with the control means. Although said manually actuable means may be actuated by the healthcare personnel, it is principally intended to be actuated by the patient itself since the patient is the best to be aware of an arising onset of hypotension. Consequently, he or she can take action before the problem becomes manifest.

5. *Inventive step (main request)*

For the assessment of inventive step, the person skilled in the art has to consider documents which deal with an identical or analogous problem and also in neighbouring or broader technical fields (cf. T 176/84, OJ EPO 1986, 50). Therefore, the skilled person will consider document D7, in which it is known to trigger the administration of a medication by the patient itself when he or she feels the need for it. The fact that infusion of analgesic medication is more specifically concerned in this document has no bearing in the present case, since the controlled delivery of

sodium to the dialysate in an hemodialysis apparatus is already known from the closest prior art D2 taken as a starting point to define the specific problem.

Document D7 discloses (cf. Figure 5) a dosing button 80 used as an electrical control, which the patient presses to trigger the administration of a dose of a substance when he or she feels the need for it. This "manually actuable means" is connected with the microprocessor of a programmable infusion pump 10 through a connector so provided with a set of fins 52, such that the microprocessor will not allow a dose to be dispensed unless a pre-selected time interval has elapsed since the last dose (column 3, lines 34 to 38). Expressed in other terms, said manually actuable means is connected with control means (microprocessor) and said control means is responsive to a signal generated by manual actuation of the manually actuable means for initiating delivery of the substance, in conformity with the characterising features of claim 1. Document D7, therefore, not only addresses the same problem as the present patent but also provides the skilled person with a similar solution when adhering to the functional wording of the features as claimed.

To solve the problem specified above, the skilled person would associate the microprocessor of D2, which is capable of initiating a control action, with a manually actuable means available to the patient such as the dosing button proposed in document D7, and so would arrive at the claimed subject-matter. Eventual adaptation of the D2 apparatus will not present any difficulty to a person skilled in the art so that even in the present patent the details of the connection between the manually actuable means of Figure 2 and the

remaining of the delivery and control system are neither shown nor described.

Consequently, the subject-matter of claim 1 according to the main request does not involve an inventive step within the meaning of Article 56 EPC, having regards to the obvious combination of documents D2 and D7.

6. *First and second auxiliary requests*

Claim 1 according to the first and second auxiliary requests differ from the main request by the incorporation of the features of the dependent claims 2 and 3, according to which the apparatus is housed in a housing and the manually actuable means includes a cable having a button at its distal end for generating the signal. These constructional features are considered by the Board as matter of a normal design procedure and, moreover, are known *per se* from document D7 (cf. Figures 3 and 5 and column 3, lines 21 to 27). The expression "or a remote control" added at the end of claim 1 of the first auxiliary request is optional and represents an equivalent wireless version of cable connected actuable means, still within the general competence of a skilled person. As a result, the features introduced in the first and second auxiliary requests fail to add any inventive step to the subject-matter of claim 1.

7. *Third and fourth auxiliary requests*

Claim 1 according to the third and fourth auxiliary requests differ from the main request by the incorporation of the features of the dependent claims 10 and 5, respectively. The subject of these

features is to control and restrict sodium delivery to the dialysate and the delivery interval, to prevent sodium overdosing. A similar control and safety system aiming at preventing overdosing is provided by document D7, according to which the microprocessor will not allow a dose to be dispensed upon actuating the dosing button unless sufficient time has elapsed since the last dose (cf. column 3, lines 34 to 38 and 53 to 58). Consequently, also the features introduced in the third and fourth auxiliary requests fail to confer any inventive step to the subject-matter of claim 1.

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:

V. Commare W. D. Weiß