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Datasheet for the decision of 5 November 2009

Case Number: T 1112/07 - 3.2.02

Application Number: 97921358.4

Publication Number: 0857074

IPC: A61M 1/16

Language of the proceedings: EN

Title of invention:
Hemodialysis monitoring system for hemodialysis machines

Patentee:
Baxter International Inc.

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 123(2), 84, 56

Relevant legal provisions (EPC 1973):
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Keyword:
"Added subject-matter (no, after amendment)"
"Clarity (yes, after amendement)"
"Inventive step (yes, after amendment)"

Decisions cited:
T 1067/97, T 0025/03

Catchword:
-

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Case Number: T 1112/07 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 5 November 2009

Appellant: (Opponent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 29 May 2007 rejecting the opposition filed against European Patent No. 0857074 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: S. Chowdhury
Members: C. Körber
A. Pignatelli

Summary of Facts and Submissions

I. By its decision posted on 29 May 2007 the Opposition Division decided to reject the opposition based on the grounds of lack of sufficiency, added subject-matter, and lack of inventive step, and to maintain European patent No. 0 857 074 as granted.

II. An appeal was lodged against this decision by the opponent by notice received on 11 July 2007 with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 28 September 2007.

III. Oral proceedings were held on 5 November 2009, at which the following requests were presented:

The appellant (opponent) requested that the decision under appeal be set aside and European patent No. 0 857 074 be revoked.

The respondent (patentee) requested that the patent be maintained on the basis of the set of claims submitted as the main request during the oral proceedings of 5 November 2009 held before the Board.

IV. The following documents are of importance for the present decision:

D1: WO-A-94/08641;
D2: N.-K. Man et al.: "Clinical Validation of a Predictive Modeling Equation for Sodium", Artifical Organs 9, p. 150-154 (1985);

D3: P.R. Keshaviah und S. Shaldon: "Haemodialyis monitors and monitoring", in "Replacement of renal function by dialysis", W. Drukker et al. (Eds.), Kluwer, Dordrecht, 1983, p. 230-234.

V. Claim 1 of the patentee's main request reads as follows:

"An apparatus for conducting equilibration of dialysate with a patient's blood for a patient undergoing hemodialysis, comprising:

first means of connecting to a dialysis machine (120) for receiving a flow of dialysate therefrom;

first means for connecting said apparatus to a dialyzer cartridge (106) and for directing said flow of dialysate from said dialysis machine to said dialyzer cartridge;

first means for connecting to said dialyzer cartridge and for receiving dialysate from said dialyzer cartridge;

second means for connecting to said dialysis machine for directing a flow of dialysate into said dialysis machine;

bypass means (160) selectively actuatable between two positions, a first position in which flow of dialysate is directed from said dialysis machine, through said dialyzer cartridge and returned to said dialysis machine, and a second position in which flow of dialysate is shunted away from said dialyzer cartridge so as to bypass the dialyzer cartridge and be returned to said dialyzer machine;

means adapted for measuring the concentration of metabolite in a sample of the dialysate after partial equilibration and in a sample of the dialysate after a specified time has passed;

means adapted for comparing the metabolite concentrations; and

means adapted for continuing to sample the dialysate until the difference in metabolite concentration between two successive samples is less than a specified amount."

Claims 2 to 4 are dependent claims.

VI. The argumentation of the appellant can be summarized as follows:

Features g) to i) of claim 1 (see feature breakdown given under point 2 below) were only disclosed in combination with the blood pump running and ultrafiltration taking place, these being essential features as described in all relevant parts of the description dealing with features g) to i), and also being comprised in claim 1 as originally filed. Their omission thus represented an intermediate generalisation not allowable under Article 123(2) EPC. Reference was made to decisions T 1067/97 or T 25/03 with respect to the inadmissible extraction of isolated features from combinations disclosed in specific embodiments.

Furthermore, the sampling, measuring and comparing as defined in features g) and h) was only disclosed in combination with the bypass means being in the second position, as may be seen from original claim 10.

There was also no basis in the original application documents for the attribution of the "intelligent" features g) to i), relating to the automated

measurement and evaluation, to the bypass means f), which had only been disclosed as a simple mechanical system as defined in original claim 9 and shown in Figures 7 and 8.

The addition of feature i) to granted claim 1 rendered the claim unclear under Article 84 EPC since it defined three separate means, viz. g) to h), without specifying their mutual relationship.

Starting from D2, claim 1 was distinguished by features g) to i). D2 already gave a hint that the reduction of the duration of the measurement was desirable (see lines 10 to 12 of the section entitled "Discussion" on page 152). There was also an indication in the following paragraph starting at line 15 that previous studies showed that for sodium equilibration was complete after 3 minutes. For other solutes, a measurement after 10 minutes was considered to give sufficiently accurate results. This was an indication that different metabolites required different equilibration times.

The solution according to claim 1 would have been obvious since it resided in the mere automation of steps performed manually in D2, particularly in view of the hints given on page 152, line 10 of the first paragraph of the "Discussion". Moreover, the skilled person knew that a convergence criterion as defined in feature i) had to be applied in order to assure that equilibrium has been reached.

Starting from D1, feature f) was disclosed therein, in addition to features a) to e), as may be seen from the

bottom paragraph of page 18 of D1. Moreover, such bypass means were generally known to the skilled person, as may be seen from Figure 6 of D3. Accordingly, claim 1 was distinguished over D1 by features g) to i).

The problem to be solved by features g) to i) was to provide an alternative to a single measurement after a given time for achieving an equilibrated value, as disclosed in D1. The skilled person must have carried out previous measurements in order to determine the equilibration time indicated in D1, and these must have been exactly of the kind as defined by features g) to i). Since there was no other alternative, the solution was obvious from D1 alone.

This would even be more evident if the skilled person additionally took into account that D2 indicated that a reduction of the duration of the measurement was desirable (see lines 10 to 12 of the section entitled "Discussion" on page 152). Accordingly, there was also a lack of inventive step when starting from D1 in view of D2.

VII. The argumentation of the respondent can be summarized as follows:

The features of claim 1 did not represent an unallowable intermediate generalisation. The processes denoted as "ultrafiltration", i.e. the physical transport processes across the dialyser membrane allowing for equilibration of the metabolite concentration in the dialysate with that in the blood, took place in the dialyser of the dialysis machine,

which was not part of the claimed apparatus. The blood pump was also not part of the claimed apparatus. The conditions occurring in the dialyser and in the blood pump were of no import to the definition of the claimed apparatus. Moreover, feature g) of claim 1 implied that equilibration was actually taking place during the measurement. The attribution of features g) to i) to the bypass means as defined in original claim 9 could be clearly derived from the overall content of the original description. It was not necessary to explicitly recite in features g) to i) that the bypass means was in the second position.

The addition of feature i) in claim 1 did not require further clarification.

In addition to features g) to i), claim 1 was distinguished over D2 by the second (bypass) position of the bypass means defined in feature f). The problem to be solved by features g) to i) was to obtain a reliable measurement of the concentration of any desired metabolite with minimum waste of time, irrespective of the conditions in the dialyser (competency, size, blood flow rate) and of the metabolite whose concentration was to be measured, as may be seen from paragraphs [0062] to [0064] of the specification. Accordingly, reliability of the measurement was the main issue, with the reduction of measurement time being a secondary goal. No hint towards this problem could be derived from D2.

Mere automation would only lead to replacement of the manual sampling and timing disclosed in D2 by automated measurements, but definitely not to features h) and i),

as argued by the appellant. Incorporating the results of the "previous studies" referred to in D2, showing that 3 minutes were sufficient for the equilibration of sodium, into the apparatus shown in Fig. 1 of D2, would be entirely hypothetical.

When starting from D1, it was clear that the passage on the bottom paragraph of page 18 of D1 did not disclose that the flow of dialysate shunted away from the cartridge was returned to the dialysis machine, as defined in feature f). This could also not be derived from D3 which explicitly stated (page 231, bottom of the second paragraph on the right hand column, and page 232, bottom of the penultimate paragraph of the right hand column) that the flow of dialysate shunted away from the cartridge was diverted to a drain, rather than returned to the dialysis machine.

With regard to the "previous measurements", necessarily conducted in order to determine the equilibration time indicated in D1 as argued by the appellant, possibilities other than those defined in claim 1 also existed, for instance plotting the measured values against time and determining the time necessary for reaching a plateau phase. Moreover, it had to be taken into account that with the claimed apparatus, the measurements were to be conducted and evaluated as part of an on-line dialysis treatment.

Reasons for the Decision

1. The appeal is admissible.

2. The parties used a feature breakdown of claim 1 as follows:

a) An apparatus for conducting equilibration of dialysate with a patient's blood for a patient undergoing hemodialysis, comprising:
b) first means of connecting to a dialysis machine (120) for receiving a flow of dialysate therefrom;
c) first means for connecting said apparatus to a dialyzer cartridge (106) and for directing said flow of dialysate from said dialysis machine to said dialyzer cartridge;
d) first means for connecting to said dialyzer cartridge and for receiving dialysate from said dialyzer cartridge;
e) second means for connecting to said dialysis machine for directing a flow of dialysate into said dialysis machine;
f) bypass means (160) selectively actuatable between two positions, a first position in which flow of dialysate is directed from said dialysis machine, through said dialyzer cartridge and returned to said dialysis machine, and a second position in which flow of dialysate is shunted away from said dialyzer cartridge so as to bypass the dialyzer cartridge and be returned to said dialyzer machine;
g) means adapted for measuring the concentration of metabolite in a sample of the dialysate after partial equilibration and in a sample of the dialysate after a specified time has passed;
h) means adapted for comparing the metabolite concentrations; and
i) means adapted for continuing to sample the dialysate until the difference in metabolite

concentration between two successive samples is less than a specified amount.

3. Amendments

Features a) to f) of claim 1 are based on original claim 9, with the addition of the expression "so as to bypass the dialyzer cartridge and" in feature f) which is based on page 33, lines 26 to 28 of the description as originally filed. Features g) to i) are based on page 9, lines 16 to 22, page 34, lines 19 to 25, and original claim 1. The last paragraph on page 10 provides a clear basis for linking these features to original claim 9.

The Board does not share the appellant's view that features g) to i) have only been disclosed in combination with the blood pump running while ultrafiltration is taking place, and that these features are essential and their omission thus represents an unallowable intermediate generalisation.

The term "ultrafiltration" is used in the application to denote physical transport processes across the dialyser membrane allowing for equilibration of the metabolite concentration in the dialysate with that in the blood. These processes take place in the dialyser of the dialysis machine, which is not part of the claimed apparatus, and the circumstances of their occurrence are not relevant to the structure and function of the claimed apparatus. The blood pump is also not part of the claimed apparatus. It is running when the system is in operation, but its operating condition is not decisive with respect to the

definition of the claimed apparatus. Feature g) implies that equilibration is actually taking place during the measurement, and this is fully sufficient for determining the metabolite concentration according to the concept of the invention. Consequently, the running of the blood pump and the continuation of ultrafiltration are not inextricably linked with features g) to i) of claim 1. The present situation therefore does not correspond to that underlying decisions T 1067/97 or T 25/03 cited by the appellant in this respect.

The appellant has further objected to the combination of the "intelligent" features g) to i) with the "simple" mechanical bypass means f) as defined in original claim 9 and disclosed in Figures 7 and 8. There are, however, various parts of the description providing a basis for this combination, for instance the passage already mentioned above on page 34, lines 13 to 25, or page 10, lines 16 to 19.

The original disclosure does not require claim 1 to explicitly recite in features g) to i) that the bypass means is in the second position, the fact that this position is clearly defined in the preceding feature f) is fully sufficient. Such a modification is also not necessary in view of original claim 10 which relates to the measuring of the **flow**.

For these reasons claim 1 is free from objections under Article 123(2) EPC.

4. Clarity

The addition of feature i) to claim 1 as granted does not render the claim unclear. Defining separate means adapted for performing separate operations as in features g) to i) is normal practice and acceptable, and their mutual relationship is clearly evident to the skilled person from the wording of the claim. Accordingly, the claim fulfils the requirements of Article 84 EPC.

5. Inventive step

5.1 Claim 1 is distinguished over document D2 by features g) to i), as conceded by the appellant. The respondent sees a further distinction in the second (bypass) position of the bypass means in feature f) requiring that **all** the dialysate is returned to the dialysis machine with the flow of dialysate through the dialyser cartridge being stopped, whereas in the "recirculation mode" shown in the right part of Fig. 1 of D2, dialysate is pumped by pump P at a high rate through the cartridge. However, this difference is not reflected by the wording of the claim which merely refers to "flow of dialysate" and "so as to bypass the dialyzer cartridge". Accordingly, feature f) is disclosed in D2.

The objective problem to be solved by features g) to i) is to obtain a reliable measurement of the concentration of any desired metabolite, yet with a minimum waste of time, irrespective of the conditions in the dialyser (competency, size, blood flow rate) and of the metabolite whose concentration is to be measured

(see paragraphs [0062] to [0064] of the patent specification). D2 gives a general hint that a reduction of the duration of the measurement is desirable (see lines 10 to 12 of the section entitled "Discussion" on page 152). There is also an indication in the following paragraph starting at line 15 that for sodium equilibration is complete after 3 minutes. For other solutes, a measurement after 10 minutes was considered to give sufficiently accurate results. This may be seen as an indication that different metabolites may require different equilibration times. However, there is no hint that it would be of advantage to deviate from the generally known concept of waiting for a fixed and sufficiently long period of time to obtain the equilibration sample. Moreover, the document is entirely silent about the reliability of the measurement in view of the variability of equilibration time due to the conditions in the dialyser as encountered in a dialysis centre.

With the claimed solution according to features g) to i), a sufficient degree of equilibration is assured by continuing the sampling and comparison until the difference between two successive measurements falls below a set value, i.e. within a minimum amount of time for a given metabolite in a certain dialyser in a given state of use.

The Board does not share the appellant's view that the claimed solution would be obvious in that it resides in the mere automation of steps performed manually in D2, particularly in view of the hint given on page 152, line 10 of the first paragraph of the "Discussion". Mere automation would at most lead to replacement of

the manual sampling and timing disclosed in D2 by automated measurements, i.e. to feature g) of claim 1. Incorporating the results of the "previous studies" referred to in D2, showing that 3 minutes are sufficient for the equilibration of sodium, into the apparatus shown in Fig. 1 of D2 would be hypothetical in view of the teaching that 10 minutes are needed "for other solutes". There is no hint in D2 towards including means adapted for comparing and continuing to sample until the termination criterion is met as defined in features h) and i). By means of this specific criterion, the various conditions of use occurring in practical situations in a dialysis centre can be taken into account in a reliable and effective manner. The solution in terms of features h) and i) is therefore not obvious when starting from D2 and taking into account the general knowledge of the skilled person.

5.2 It is agreed by the parties that document D1 (acknowledged in paragraph [0017] of the patent specification) fails to disclose features g) to i) of claim 1. With respect to feature f), the appellant referred to the bottom paragraph of page 18 of D1. However, this passage does not disclose that the flow of dialysate shunted away from the cartridge is **returned to the dialysis machine**, as required by feature f). Accordingly, D1 is more remote from the invention than D2.

With respect to the bypass means, the appellant has further referred to Figure 6 of D3, a textbook cited as evidence that bypass means were generally known to the skilled person. However, D3 (page 231, bottom of the

second paragraph on the right hand column, and page 232, bottom of the penultimate paragraph of the right hand column) explicitly states that the flow of dialysate shunted away from the cartridge is diverted to a **drain**, rather than returned to the dialysis machine, as required by feature f). Consequently, D3 is of no further relevance.

There is no justification for the less ambitious reformulation of problem as suggested by the appellant, namely to simply provide an alternative to the single measurement after a given time for achieving an equilibrated value. The objective problem is as indicated above under point 5.1, 2nd paragraph, and is credibly solved by the distinguishing features. D1 does not give any hint towards this problem.

It was further argued that the skilled person must have carried out previous measurements in order to determine the equilibration time indicated in D1, and that these must have been exactly of the kind as defined by features g) to i). This is not the case, however, since other possibilities exist, for instance plotting the measured values against time and determining the time when a plateau phase is reached. Moreover, it has to be taken into account that the measurements are to be conducted and evaluated as part of an on-line dialysis treatment.

Accordingly, the subject-matter of claim 1 is not obvious from D1 and the general knowledge of the skilled person for the same reasons indicated above under point 5.1.

5.3 The Board also does not follow the obviousness attack of the appellant starting from D1 in combination with D2, indicating that a reduction of the duration of the measurement is desirable (see lines 10 to 12 of the section entitled "Discussion" on page 152). As already mentioned above, there is no hint in D2 to deviate from the generally known concept of waiting for a fixed period of time to obtain the equilibration sample, and the document is entirely silent about the variability of equilibration time due to the conditions in the dialyser as encountered in a dialysis centre. Moreover, since document D2 also fails to disclose features g) to i), its combination with D1 does not lead to the subject-matter of claim 1.

5.4 For the above reasons, the subject-matter of claim 1 is based on an inventive step (Article 56 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 the first instance with the order to maintain the patent on the basis of the following documents:

   Claims 1 to 4 according to the main request filed during the oral proceedings before the Board;

   Description pages 2 to 16 as granted and published;

   Figures 1 to 13 as granted and published.

The Registrar: The Chairman:

C. Eickhoff S. Chowdhury