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D E C I S I O N
of 5 October 2000

Case Number: T 0132/98 - 3.2.2

Application Number: 92915292.4

Publication Number: 0547210

IPC: A61M 1/16

Language of the proceedings: EN

Title of invention:
Method and means for dialysis

Patentee:
HOSPAL LTD.

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 56, 111(1)

Keyword:
"Late-filed documents (partially admitted)"
"Remittal of the case (no)"
"Inventive step (no)

Decisions cited:
T 0476/89, T 0238/92, T 1002/92, G 0009/91

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0132/98 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 5 October 2000

Appellant: (Opponent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 1 December 1997 rejecting the opposition filed against European patent No. 0 547 210 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: M. G. Noël
J. C. M. De Preter

Summary of Facts and Submissions

I. Following an opposition filed by the appellant against European patent No. 0 547 210 on the ground of lack of inventive step, the Opposition Division decided on 1 December 1997 to reject the opposition and to maintain the claims as granted.

II. The state of the art was represented, in particular, by documents:

D1: DE-A-2 825 134, and

D2: "Optimal Hemodialysis Programming by a Mathematical Model", by E. Sarti et al., pages 602 to 604, Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biological Society, 4 to 7 November 1988, G. Harris, New Orleans.

III. The appellant lodged an appeal on 2 February 1998 against the first instance's decision. With its statement of grounds, filed on 27 March 1998, a new document was submitted to support its view:

E6: "Ultrafiltration" from "Adaptive Control" pages 468 to 475, chapter 12.6, by K.J. Aström and B. Wittenmark, Addison-Wesley Publishing Company, Reading, Massachussets, 1989,

IV. The respondent (patent proprietor) replied by letter dated 14 August 1998 and filed an additional set of claims according to an auxiliary request.

V. The appellant replied by letters dated 19 January and

23 April 1999, successively, and filed further three new documents, one of which being:

E7: "A digital Computer Model for optimal programming of hemodialytic treatment", C. Lamberti et al., The International Journal of Artificial Organs, vol. 11, No. 4, 1988, pages 235 to 242.

Besides objections related to inventive step, lack of novelty of claim 1 (main request) was also raised based on the disclosure of document E7.

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

The respondent requested that documents E6 to E9 should not be taken into consideration and that, if these documents are to be considered, the case be remitted to the first instance for further prosecution and, in this case, that the appellant pay the costs of the oral proceedings of 5 October 2000 and of all future oral proceedings until the case is settled.

It further requested that, whatever decision is taken about the admissibility of documents E6 to E9, the appeal be dismissed (main request) or that the patent be maintained in amended form on the basis of claims 1 to 31 submitted by letter of 14 August 1998 (auxiliary request).

VII. Oral proceedings were held on 5 October 2000.

(i) The appellant submitted that the documents filed during the appeal proceedings were to be admitted

owing to their great relevance and because they were successively filed to overcome the reasons set out in the contested decision or in response to the respondent's contentions. In particular, the disclosure in document E7 was of such a relevance as to even deprive the subject-matter of claim 1 (main request) of any novelty. Otherwise, document E7 was still usable, like document D2, against the inventive step of claim 1, in combination with the closest prior art document D1 which already disclosed the precharacterising features of said claim.

Document E7 disclosed, in particular with reference to Figure 10, a closed-loop dialysis control system provided with a physiological controller based on a mathematical model for automatically adjusting the set-points of the dialysis machine parameters. The model was adapted continuously to the patient's response to the dialysis treatment by means of feed-back control loops coming from the patient. Further, since E7 disclosed a number of variables and parameters entering the mathematical model of the patient-dialysis unit system, the features added to claim 1 according to the auxiliary request did not add anything inventive to the main request.

(ii) The respondent submitted that late-filed documents E6 to E9 were to be disregarded because they were no more relevant than documents already on file. Consequently, their admission would result in an intolerable delay of the proceedings. If, nevertheless, these documents were considered by the Board, the case should be remitted to the

Opposition Division for further prosecution and the costs incurred by the respondent for the oral proceedings paid by the appellant.

Document E7 like document D2 referred to the achievement of a closed-loop dialysis unit with continuous adjustment of the set-points as an ideal and ambitious goal, however not yet carried out at the time the articles were reported. In fact, document E7 like D2 disclosed an open-loop dialysis system, in which one or more stable profiles of a patient were pre-programmed in the memory of the computer, so that the model parameters remained unchanged or, at the very most, varied by steps during the treatment, under the control of a physician. The contribution of the present invention with respect to the prior art was, actually, to continuously and automatically adjust the model parameters on the basis of the patient's response to the dialysis treatment, by way of adaptive control. This feature was not disclosed by the prior art documents.

The claims according to the auxiliary request were still more remote from the state of the art in that the patient parameters were represented by the coefficients of a mathematical model of the dialysis unit-patient system.

VIII. Independent claims 1 (device) and 18 (method) according to the main request read as follows:

"1. A dialysis system comprising a dialysis unit (11) which is connected when in use to a patient subjected

to dialysis treatment, a memory (15) for storing desired values (Y_D), which vary in the course of time, of a patient parameter, at least one sensor (25) for measuring the actual values (Y) of the said patient parameter and a control unit (13) connected to the said memory (15) and to the said sensor (25) to receive the said actual values (Y) and desired values (Y_D) of the said patient parameter, the said control unit (13) being capable of determining the value (U) of at least one machine parameter passed to the said dialysis unit (11) to control the said patient parameter, characterised in that the said control unit (13) forms an adaptive controller comprising estimating means (31) capable of estimating the value of patient parameters (K) correlating with the patient's response to dialysis treatment and control means (32) for determining the value (U) of the said at least one machine parameter on the basis of the estimated values of the said patient parameters (K)."

"18. A method of monitoring a dialysis unit (11) which is connected when in use to a patient subjected to dialysis treatment, comprising the stages of:

- storing in memory desired values (Y_D) of a patient parameter, which vary in the course of time
- measuring actual values (Y) of the said patient parameter and,
- controlling the operation of the said dialysis unit (11) through at least one machine parameter (U) to cause the said patient parameter to adopt the said desired values,

characterised in that the said stage of the controlling of the operation is an adaptive control which includes the estimation (62) of patient parameters (K) correlating with the patient's response to treatment

and the control (63) of the machine parameter (U) on the basis of estimated values of the said patient parameters."

Independent claims 1 and 18 according to the auxiliary request differ from corresponding claims of the main request only by the incorporation, in the characterising portion of the respective claims, of the expression "and representing the coefficients in a predetermined mathematical model of a dialysis unit/patient system (5), and", after the term "treatment".

Reasons for the Decision

1. The appeal is admissible.

2. *New documents and associated requests*

2.1 Among documents E6 to E9 cited by the appellant during the appeal proceedings, document E6 was filed along with the statement of grounds in reaction to a finding of the Opposition Division in the contested decision. According to the case law of the Boards of Appeal (T 476/89, 10 September 1991, section 6.3 and T 238/92, 13 May 1993, section 2.2, both not published), a document which is presented for the first time with the statement of grounds is not considered as "late-filed" and, therefore, is admissible, if it serves as evidence of a feature considered in the contested decision as essential for the assessment of inventive step. In the present case, document E6 was cited as an effective evidence that adaptive control was also used in the specific field of dialysis control units.

Document E7 was introduced by the appellant in response to the respondent's reply to the statement of grounds. This document is already referred to in document D2 (chapter "Model Structure", reference [6], pages 602 and 604) in which it is reported that a new, more appropriate, mathematical model was needed and already described in document [6] (E7) in order to avoid the drawbacks presented by the previous model (references [1 to 5]. Consequently, document D2 could only be properly understood in the light of document E7, which was implicitly incorporated by reference in document D2 and, therefore, could not be ignored by the parties from the very beginning of the opposition proceedings. Consequently, document E7 is not late-filed.

Moreover, since documents E6 and E7 are more relevant than documents already on file because there are, *prima facie*, clear reasons to suspect that these new documents would prejudice the maintenance of the patent (cf. T 1002/92, OJ EPO 1995, 605, section 3.4) and further considering that these documents were already discussed by both parties in their written submissions, the Board, at the oral proceedings, decided to consider documents E6 and E7 in the present proceedings.

In contrast thereto, documents E8 and E9 were disregarded due to their minor relevance.

2.2 From the foregoing, it results that the respondent's request for remittal of the case to the first instance was not justified in the present circumstances. Therefore, the Board decided to continue with the case on its own motion for further prosecution on the substantive issues, exercising its discretion provided by Article 111(1) EPC.

As a further consequence, the respondent's request for apportionment of costs in its favour, which is conditional on remittal of the case, must also fail.

3. *Closest prior art and novelty*

3.1 During the appeal procedure the appellant for the first time challenged the novelty of the subject-matter of claim 1, having regard to the disclosure in document E7. Since, however, the respondent and patent proprietor did not agree to the introduction of this fresh ground for opposition, it could not be dealt with and, therefore, was refused by the Board at the oral proceedings (cf. G 9/91, OJ EPO 1993, 408, section 18).

3.2 Document D1 represents the closest prior art since it discloses all the features contained in the pre-characterising portion of claim 1. In particular, D1 discloses (cf. page 18 and Figure 4) a dialysis system monitored by a closed-loop feedback control unit (CPU 32) which receives measurement values of the patient provided by a blood analyser 36. During the dialysis treatment the analytical results are compared with pre-programmed data entered into the memory of the central processing unit (CPU) by the attending physician, which data are representative of the particular patient profile. The dialysis machines parameters are then controlled by the CPU in order to maintain said profile and to perform dialysis in a way acceptable for the patient.

However, the control performed in document D1 is not adaptive in the meaning that the set values pre-programmed in the memory bank of the CPU are not variable in time, so that the feed-back control

described in this document does not take account of any change in the behaviour of the individual patient during treatment.

With respect to document D1, the subject-matter of claim 1 differs by its characterising portion, i.e. by all features characterising the adaptive controller. Therefore, the subject-matter of claim 1 is novel.

4. *Inventive step (main request)*

4.1 The characterising clause of claim 1 represents the solution of the technical problem underlying the present patent (cf. page 2, lines 52 to 54) of increasing the patient's wellbeing by reducing undesirable side effects to a minimum, in particular the occurrence of severe hypotension, due to the fact that conventional dialysis control systems such as the one known from document D1 do not take any account of the individual patient reactions during the treatment.

This problem is solved by means of a feedback control which, at individual instants during treatment, takes account of the behaviour of the individual patient, using a mathematical model of the patient-dialysis unit system with parameters which vary in time. Therefore, the model is completely individualised by values of its parameters which describe the patient's response to dialysis treatment in a quantitative way (cf. page 3, lines 16 to 20 and page 5, lines 51 to 56).

The controller as claimed is said to be adaptive in that the instantaneous values of the patient parameters, which are correlated with the patient response to dialysis treatment and are represented by

coefficients K_i of the mathematical model of the patient-dialysis unit system 5, are continuously calculated during the dialysis in order to modify the desired values (set-points) of the machine parameters, whereas initial values relate to an average patient profile or result from the behaviour of the particular patient in a previous session. More simply, according to the adaptive control at issue, the set values of the machine parameters are continuously and automatically adjusted in response of the patient's behaviour.

4.2 Document E7 relates to a digital computer model for optimal programming of hemodialytic treatment. In the paragraph "Introduction" (page 235), at first traditional dialysis systems with their associated drawbacks are presented, going on to describe the achievement of automatic adjustment of the set-points of the dialysis unit in relation to measures that represent the patient's wellbeing, particularly as regards the drop of arterial pressure (hypotension). This automation is said to be based on a reliable mathematical model for the patient undergoing treatment.

This system is discussed in a more detailed manner on page 240 with reference to Figure 10, where it is specified that a true retroactive system (such as that illustrated on Figure 10) is able to adjust the set-points of the dialytic unit continuously and automatically on the basis of information coming from the patient. This statement is confirmed at the end of the discussion (page 242), where it is reiterated that in closed-loop dialysis (such as that of Figure 10) the artificial kidney sets the most suitable set-point values for the patient's well-being, moment by moment.

This corresponds exactly to the definition of adaptive control in the meaning of the patent in suit.

Document E7 further states (page 240, paragraph bridging left and right columns) that, in practice, the known dialysis device (that of Figure 10) is equipped with an "electronic expert operator" who records, elaborates and intervenes in a series of situations that can be critical for the patient. This aim can only be achieved with a model of the patient-artificial kidney system. Such a system is illustrated on Figure 10 of document E7 by double-arrow between the block "traditional dialysis unit" and the block "patient". It is similar to the patient-dialysis unit exchange system 5 referred to on Figure 2 of the present patent. As a consequence, it is obvious that the "physiological controller based on mathematical model" represented on Figure 10 of E7 works in the same way as the "adaptive control unit" according to the patent, including in the same unit estimating means for estimating the value of patient parameters (feed-back loops from the patient) and control means for determining the value of the machine parameters (set-points).

It results therefrom that the characterising features of claim 1 are known from document E7. The fact that in document E7 the closed-loop dialysis system is presented as a future, ideal solution, has no consequence on the relevance of its teaching, since the disclosure is presented with sufficient information to suggest the not less generally defined solution of claim 1. For the comparison between an invention and a prior art document, the same standard of generalisation applies when assessing inventive step.

4.3 Therefore, the Board is satisfied that the subject-matter of claim 1 according to the main request is not inventive vis-à-vis the combination of documents D1 and E7, contrary to the provisions of Article 56 EPC.

5. *Auxiliary request*

Claim 1 according to the auxiliary request only differs from the main request by the introduction of the following feature in the characterising portion:

"and representing the coefficients in a predetermined mathematical model of a dialysis unit/patient system (5)".

This expression is not mentioned as such in document E7. Its teaching is, however, clearly suggested in the paragraph of page 240 already quoted above: "This aim cannot be achieved unless there is a model of the patient-artificial kidney system". As illustrated on Figure 10, the output of the physiological controller controls the "set-points" of the dialysis unit, continuously corrected in relation to the patient parameters received from the patient via the feed-back loops. Having in mind the numerous variables and parameters used in the mathematical model (page 237, "list of symbols"), the skilled person had no other choice than automatically adjusting the coefficients of said model as a function of the patient's reaction to the treatment.

Consequently, the additional feature incorporated in claim 1 according to the auxiliary request fails to add any inventive step to the subject-matter of claim 1 of the main request. Therefore, the provisions of

Article 56 EPC are not met, either.

6. Since a patent cannot be maintained partially, after the refusal of the device claims according to any request, examination of the independent method claims can be dispensed with. As a consequence, the patent must be revoked in its entirety.

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