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**D E C I S I O N**  
**of 30 March 2000**

**Case Number:** T 1074/98 - 3.2.2

**Application Number:** 93100634.0

**Publication Number:** 0547025

**IPC:** A61M 1/14

**Language of the proceedings:** EN

**Title of invention:**

Method for determining a concentration of a substance in blood  
or the dialysance of a dialyser

**Patentee:**

GAMBRO AB

**Opponent:**

Fresenius Medical Care Deutschland GmbH

**Headword:**

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**Relevant legal provisions:**

EPC Art. 76(1); 100(c)

**Keyword:**

"Extension of the claimed subject-matter of a patent granted  
on a divisional application beyond the content of the earlier  
application (no) "

**Decisions cited:**

T 0823/96, T 0548/98, T 0873/94, G 0002/88

**Catchword:**

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Case Number: T 1074/98 - 3.2.2

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.2  
of 30 March 2000

**Appellant:** Fresenius Medical Care Deutschland GmbH  
(Opponent) Frankfurter Strasse 6-8  
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**Representative:** Luderschmidt, Wolfgang, Dr. Dipl.-Chem.  
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**Respondent:** GAMBRO AB  
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**Representative:** Lejeune, Daniel  
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**Decision under appeal:** Interlocutory decision of the Opposition Division  
of the European Patent Office posted 30 September  
1998 concerning maintenance of European patent  
No. 0 547 025 in amended form.

**Composition of the Board:**

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

## Summary of Facts and Submissions

- I. European patent No. 0 547 025 was granted on 12 June 1996 on a European patent application originating from a division of an earlier patent application published as EP-A-0 330 892.
- II. In consequence of an opposition filed by the appellant the Opposition Division decided on 30 September 1998 to maintain the European patent in amended form. The opposition was based on the grounds of Article 100(c) EPC, second alternative (patent subject-matter extending beyond the content of the earlier application as filed).
- III. On 13 November 1998, the appellant lodged an appeal against this decision. In its statement of grounds filed on 6 February 1999, the objection on the ground of Article 100(c) EPC was maintained and, for the first time, novelty of the subject-matter of claim 1 was contested vis-à-vis a new prior art document cited on the basis of Article 54(3) EPC.
- IV. The respondent (patent proprietor) replied to the appellant's contention on 16 August 1999 and filed a new set of amended claims as an auxiliary request. It also objected to consideration of the new ground of opposition under Article 100(a) EPC raised by the appellant.
- V. Oral proceedings were held on 30 March 2000, at the beginning of which the Board announced that the new ground of opposition would not be considered in the absence of the respondent's agreement. The parties argued as follows:

(i) the appellant:

- the amendments made to claim 1 cannot be clearly and unambiguously deduced from the content of the earlier application. Therefore, they extend beyond the content of said application and are not acceptable according to Article 100(c) EPC, second alternative.
- Claim 1 relates to a method for determining the concentration of a substance in the blood, whereas the earlier application was directed to a dialysis system, i.e. a claim of narrower category.

The formula for determining the factor K indicated at column 3, line 28, of the earlier application and its respective description are disclosed in terms which are too general to adequately support the more specific subject-matter of claim 1. In particular, a dialysis liquid is disclosed in the earlier application, the concentration of which is altered by steps so as to determine K continuously from a comparison between two conductivity measurements on the same liquid, whereas, according to the method as now claimed, a further step of successively measuring the conductivities on two dialysis liquids having different concentrations is required.

Consequently, claim 1 is supported neither directly nor implicitly by the disclosure of the earlier application. Incidentally, the common general knowledge of the skilled person is irrelevant to the assessment of what is implied by the disclosure of the earlier application (cf. T 823/96).

- The method according to claim 1 is actually based on the solution of an equation whose novelty with respect to the earlier application was already recognised by the Board in a previous related case (T 548/98). Therefore, claim 1 has been amended by incorporating new matter, i.e. matter going beyond the content of the earlier application as filed.

(ii) the respondent:

- the earlier application discloses not only a dialysis system in terms of a device for performing a dialysis treatment but also a method for controlling the composition of the dialysis liquid and thereby, the composition of a substance in the blood.

In particular, there is disclosed in column 3 a method for determining the factor K, starting from a formula which contains two unknown quantities. It is self-evident that K can only be obtained from specific values of conductivities taken from at least two dialysis liquids having different concentrations. As a consequence, the method claimed is implicitly disclosed by the earlier application, although a different wording is used (cf. T 873/94).

- Decision T 548/98 referred to by the appellant in relation to the novelty test is irrelevant to the present case because the equation opposed by the appellant is not the subject-matter of claim 1 in suit. Contrary thereto, the above mentioned decision provides a detailed and useful analysis of the earlier application for determining the extent of the disclosure, including all information implicitly contained in said document such as the steps of the method as claimed. It

results therefrom that the subject-matter of claim 1 does not extend beyond the content of the application as early filed.

VI. At the end of the oral proceedings the requests were as follows:

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

The respondent requests that the appeal be dismissed (main request) or that the decision under appeal be set aside and the patent maintained in amended form with claims 1 to 4 submitted on 16 August 1999 (auxiliary request).

VII. Claim 1 according to the main request reads as follows:

"A method for determining a concentration of a substance in the blood of a patient undergoing a dialysis treatment in an artificial kidney and/or the actual dialysance for said substance of the artificial kidney, the artificial kidney comprising an extracorporeal blood circuit connected to a dialyzer having a semipermeable membrane delimiting a first compartment for the circulation of blood on one side of the membrane and a second compartment for circulating a dialysis liquid on the other side of the membrane, characterized by the steps of:

- circulating successively in the second compartment of the dialyzer a first and a second dialysis liquid having different concentrations of the substance, the first and second liquid differing only by the concentration of the substance,

- measuring in the first and second dialysis liquids the conductivity or the concentration of the substance upstream and downstream of the dialyzer, and
- calculating from the measured conductivity or concentration of the substance in the first and second dialysis liquids, the concentration of the substance in the blood at the inlet of the dialyzer and/or the actual dialysance of the artificial kidney."

### **Reasons for the Decision**

1. The appeal is admissible.
2. *Extension of the subject-matter of claim 1 (main request)*
  - 2.1 The objection of lack of novelty was raised by the appellant for the first time in its grounds of appeal. In this stage of the proceedings, a newly raised ground of opposition can only be considered with the consent of the proprietor. This consent has been denied.

Therefore, in the present case, the only ground of opposition to be considered is that of Article 100(c) EPC, second alternative. In particular, the question to be examined is whether claim 1 in suit has been amended so as to extend beyond the content of the earlier application as filed.

- 2.2 The earlier application (published as EP-A-0 330 892) was analysed in detail as prior art document D1 in a previous related case T 548/98 in which the same parties were involved.

The divisional application filed subsequently resulted in the present patent under consideration. The descriptions of both the earlier and the divisional applications are identical. The applications differ from each other only in that the claims to the earlier application relate to a dialysis system whereas those to the divisional application refer to the method for determining a concentration of a substance in the blood.

During the examination and opposition proceedings of the patent the introductory part of the description was adapted to provide consistency with the method claims as previously amended and the remaining parts of the description were recasted so as to replace "a dialysis system" by "a dialysis method" wherever it was necessary.

A change of category of claims is not prohibited by the EPC if the amended claims which result in the new category are supported by the application as originally filed within the frame allowed by Article 123(2) EPC. This is the case here since the earlier application describes a system which is, typically, a mixed category, i.e. including features relating to both physical entities and physical activities. As mentioned in G 2/88, OJ EPO 1990, 93, section 2.2, there are no rigid lines of demarcation between the various possible forms of claims. Since, moreover, the description of the earlier application discloses the invention as well in terms of means of a device as in terms of steps of a method, in particular for determining the relative dialysance through the factor K, the respondent was



entitled to file a divisional application more specifically directed to the method performed by the dialysis system as disclosed in the earlier application.

- 2.3 The preamble of claim 1 consists of a combination of the preambles of claims 1 and 2 according to the divisional application as filed. The first part of this method claim includes features of a device such as an artificial kidney, blood and dialysis circuits, and a dialyser having a semipermeable membrane for dividing the dialyser into compartments, all means necessary for performing the subsequent steps of the method for determining the concentration of a substance in the blood of a patient undergoing a dialysis treatment.

All these means are fairly supported by the description of the earlier application.

- 2.4 The characterising portion of claims 1 comprises essentially the following steps:

- circulating successively in the dialysis circuit a first and a second dialysis liquid, having different concentrations of the substance;
- measuring the conductivities (concentrations) of the first and second dialysis liquids upstream and downstream of the dialyser;
- calculating from the concentrations previously measured, the concentration of the substance in the blood.

The three method steps outlined above are derivable partly directly, partly implicitly from the following passages of the earlier application as filed (published version): from column 3, line 17 to column 4, line 8;

column 4, lines 44 to 54; claims 1 to 3, 8 and 12. As it is clearly explained in decision T 548/98 which provides a detailed analysis of the earlier application (formerly identified as document D1), the formula

$$C_{dout} = C_{din} + (C_{bin} - C_{din}) \cdot K$$

is used first to calculate K, which is a proportionality constant representative of the relative dialysance and then C<sub>bin</sub>, which is the conductivity or the concentration of sodium (the substance) in blood, the remaining values C<sub>din</sub> and C<sub>dout</sub> (conductivities of the dialysis liquid before and after the dialyser) being known. According to the description (cf. column 3, line 52 to column 4, line 8) the factor K can be determined continuously by a regular change (by steps) of the conductivity of the dialysis liquid. At each change, a measure of K is obtained from a comparison between the conductivities measured before and after the dialyser, respectively.

Since the equation above has two unknown quantities (K and C<sub>bin</sub>) one of them can be eliminated through a well known mathematical process by solving a system formed with two equations obtained from two specific values of C<sub>din</sub> and C<sub>dout</sub>, such as those measured at each change before and after the dialyser. The calculations can be easily performed within the microprocessor 61, as further described in the best mode of carrying out the invention (column 7, lines 8 to 28). Having regard to the technical means at disposal in the description, there is no other possibility for calculating K from the above-mentioned equation.

Moreover, as stated in column 4, lines 4 to 8, "these changes are so rapid...and so small that they do not notably affect the aforementioned formula". This passage confirms the fact that K is calculated from two

successive dialysis liquids having neighbouring concentrations, a prerequisite for K to be considered as a constant in the meanwhile. Since, in each state (at each change) the conductivities are measured before and after the dialyser, it results that four measurements are provided, in conformity with the general meaning of the subject-matter of claim 1.

It follows from the above considerations that the claimed method is sufficiently disclosed in the earlier application since, for a skilled person the general disclosure thereof at least implies all the claimed features. In particular, the processing of the formula necessarily implies that successive conductivity measurements are made on the dialysis liquid, respectively before and after the dialyser and for two different states of concentration. These two states are distinguished in claim 1 by the expression "first and second dialysis liquid having different concentrations". Therefore, claim 1 states with other words nothing but what is unambiguously disclosed in the application.

- 2.5 In the case of a divisional application the comparison between the wording of claim 1 and the disclosure of the earlier application, for the assessment of Articles 100(c) and 76(1) EPC, does not require a literal comparison of the respective contents. Also, the application of a novelty test is not always appropriate (cf. T 873/94, OJ EPO 1997, 456, sections 2.2 and 3.1). In the present case, the disclosure of the earlier application is sufficient to support the subject-matter of claim 1 as amended, as demonstrated above.

Further, the method as claimed is generally worded with terms which differ substantially from the specific equation for calculating K referred to by the appellant

in its letter of 17 January 2000 in relation to the previous case T 548/98. Consequently, the appellant's arguments are irrelevant to the present case.

The above considerations are also in line with the findings in case T 823/96, (28 January 1997, not published) referred to by the appellant. In this decision (cf. section 4.5) it is explained that it is not precluded to refer to common general knowledge in deciding what is implied by the explicit disclosure of a document.

- 2.6 From the foregoing, it results that the subject-matter of claim 1 according to the main request and, therefore, the subject-matter of the patent originating from the divisional application do not extend beyond the content of the earlier application as filed, in accordance with Article 100(c) EPC, second alternative.

## Order

**For these reasons it is decided that:**

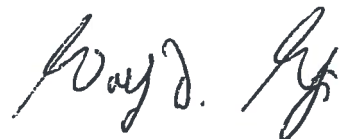
The appeal is dismissed.

The Registrar:



V. Commare

The Chairman:



W. D. Weiß