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Datasheet for the decision of 14 January 2019

Case Number: T 0046/12 - 3.3.01

Application Number: 00965346.0

Publication Number: 1218039

IPC: A61M1/16, A61K31/19

Language of the proceedings: EN

Title of invention:
USE OF HIGH CITRATE DIALYSATE

Patent Proprietor:
Advanced Renal Technologies

Opponents:
Fresenius Medical Care Deutschland GmbH
Gambro Lundia AB

Headword:
High concentration citrate dialysate/RENAL TECHNOLOGY

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
Main request and auxiliary request: amendments - extension beyond the content of the application as filed (yes)

Decisions cited:
G 0002/10, T 0629/90, T 0823/96, T 0590/07

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0046/12 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 14 January 2019

Appellant: (Patent Proprietor)	Advanced Renal Technologies 40 Lake Bellevue Suite 100 Bellevue, WA 98005 (US)
Representative:	Gowshall, Jonathan Vallance Forresters IP LLP Skygarden Erika-Mann-Strasse 11 80636 München (DE)
Respondent: (Opponent 2)	Gambro Lundia AB P.O.Box 10101 220 10 Lund (SE)
Representative:	J A Kemp 14 South Square Gray's Inn London WC1R 5JJ (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 11 November 2011 revoking European patent No. 1218039 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Lindner
Members:	G. Seufert
	P. de Heij

Summary of Facts and Submissions

I. The patent proprietor (appellant) lodged an appeal against the decision of the opposition division revoking the European patent No. 1 218 039.

II. The present decision refers to the following documents:

R5 Viganò *et al*. in Drukker, Parsons and Maher "Replacement of Renal Function by Dialysis", fourth edition, 1996, Kluwer Academic Publishers, Dordrecht (NL), 326 to 328;

R17 R. J. Caruana, D. M. Keep in Handbook of Dialysis, second edition, 1994, Little, Brown and Company, Boston (US), Chapter 7 "Anticoagulation", pages 121 to 135.

III. Notices of opposition were filed by opponents 1 and 2 requesting revocation of the patent in suit on the grounds of lack of novelty and inventive step, insufficiency of disclosure and added subject-matter (Article 100(a), (b) and (c) EPC).

IV. The decision under appeal was based on the set of claims as granted (main request) and sets of claims according to first and second auxiliary requests filed at the oral proceedings before the opposition division.

The opposition division found that the subject-matter of the main request and first auxiliary request extended beyond the content of the application as originally filed. The subject-matter of the second auxiliary request was held to comply with Articles 123(2), 83 and 54 EPC, but was considered to be obvious in the light of the available prior art.

V. With the statement of grounds of appeal, the appellant filed a set of "First amended claims" as main request and a set of "Second amended claims" as auxiliary request. The main request is identical to the second auxiliary request underlying the decision under appeal. The appellant also filed additional evidence to support its arguments concerning inventive step.

Claim 1 of the main request reads as follows:

"1. A dialysate composition comprising citrate at a concentration ranging from 2.4 to 20 mEq/L, calcium at a concentration ranging from 2.5 to 5 mEq/L and magnesium at a concentration ranging from 1 to 2 mEq/L for use in performing dialysis on a patient in need thereof, wherein the dialysis is performed with the dialysate composition in the absence of systemic administration of anticoagulant to the patient; and the dialysis is performed with the dialysate composition in a dialyzer."

Claim 1 of the auxiliary request differs from claim 1 of the main request in that the feature "**and further comprising selecting a patient that is heparin-free, and maintaining that patient in a heparin-free state while performing dialysis on that patient**" has been added.

VI. In its reply to the statement of grounds of appeal, opponent 1, who subsequently withdrew its opposition (see point IX below), argued that the subject-matter of the main request extended beyond the content of the application as originally filed, was insufficiently disclosed and lacked novelty and inventive step. The same objections and an additional objection of lack of clarity were raised against the auxiliary request.

VII. In its reply to the statement of grounds of appeal, opponent 2 (respondent) argued that the subject-matter of the main request and the auxiliary request lacked an inventive step. It also raised an objection of added subject-matter against the auxiliary request.

VIII. With letter dated 26 November 2012, the appellant provided additional arguments and evidence in response to the submissions by opponent 1 and the respondent-opponent 2.

IX. With letter dated 15 January 2016, opponent 1 withdrew its opposition.

X. In a communication dated 16 August 2018, the board, acceding to a request by the appellant (see letters of 19 July 2018 and 2 August 2018), notified the parties that the oral proceedings scheduled for 5 November 2018 were rescheduled to 14 January 2019. A communication pursuant to Article 15(1) RPBA, in which the board gave its preliminary opinion, was annexed to the notification.

As far as relevent to the present decision, the board indicated that the feature "in the absence of systemic administration of anticoagulant in the patient" was only disclosed in the context of a particular group of patients. A general disclosure as to the absence of systemic administration of an anti-coagulant was not clearly and unambiguously derivable from the pages relied on by the opposition division. The same applied *mutatis mutandis* to the auxiliary request.

XI. After oral proceedings had been rescheduled upon request by the appellant, the appellant and the

respondent informed the board by letters of 12 December 2018 and 6 December 2018 respectively that they would not be attending the oral proceedings. No observations, comments or arguments with respect to the substantive issues raised in the board's communication annexed to the communication of 16 August 2018 were provided.

XII. The appellant did not provide any arguments to rebut the objection of added subject-matter of the main request raised by opponent 1 in its reply to the statement of grounds of appeal. Nor did the appellant provide any arguments in reply to the board's objection raised in the communication pursuant to Article 15(1) RPBA.

Regarding the auxiliary request, the appellant argued that the basis for the feature "selecting a heparin-free patient and maintaining that patient in a heparin-free state while performing dialysis on that patient" could be found in claim 7 of the application as originally filed.

XIII. No argument with regard to the compliance of the main request with Article 123(2) EPC were provided by the respondent.

Concerning the auxiliary request, the respondent argued that there was no disclosure in the application as filed that dialysis should be performed using the claimed dialysate composition in the absence of systemic administration of anticoagulant in a patient and also that the patient was heparin free and should stay heparin-free during dialysis. The two aspects were mentioned on page 4, lines 2 to 16 but there was no suggestion of taking them together. Claim 7 as

originally filed, on which the appellant relied, referred back to claims 1 to 4. None of them disclosed the absence of systemic administration of an anticoagulant to the patient. The examples were silent as to the heparin status of the patients.

XIV. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of a set of claims according to the "First amended claims" (main request) or, alternatively, that the patent be maintained on the basis of the set of claims of the "Second amended claims" (auxiliary request), both sets of claims filed with the statement of the grounds of appeal.

XV. The respondent requested that the appeal be dismissed.

XVI. At the end of the oral proceedings, which took place as scheduled on 14 January 2019, the decision of the board was announced.

Reasons for the Decision

1. The appeal is admissible.

2. Non-appearance at the oral proceedings

2.1 The appellant and the respondent decided not to attend the oral proceedings before the board to which they had been duly summoned (see point XI above).

2.2 According to Rule 115(2) EPC, oral proceedings may continue in the absence of a duly summoned party. Further, pursuant to Article 15(3) of the Rules of Procedure of the Boards of Appeal (RPBA), the board is

not obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned. Such party may then be treated as relying only on its written case. In deciding not to attend oral proceedings, the appellant chose not to avail itself of the opportunity to present its observations and counter-arguments orally.

2.3 The appellant was deemed to have expected that, in line with established case law (e.g. T 629/90, point 2 of the Reasons), during the oral proceedings, the board could consider any objections and arguments raised by the respondent, opponent 1, before it withdrew its opposition, and by the board in its communication. The board concludes that the appellant had an opportunity to comment on the grounds and evidence on which the board's decision, arrived at the oral proceedings, was based. Therefore, the board was in a position to take a final decision at the oral proceedings despite the absence of the duly summoned appellant.

Main request ("First amended claims")

3. Amendments

3.1 According to established jurisprudence of the boards of appeal, amendments can only be made within the limits of what the skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole application as originally filed (G 2/10, OJ EPO, 2012, 376, point 4.3 of the Reasons).

The subject-matter must be at least implicitly disclosed. The term "implicit disclosure" should not be

construed to mean matter that does not belong to the content of the technical information provided by a document but may be rendered obvious on the basis of that content. The term "implicit disclosure" relates solely to matter which is not explicitly mentioned, but is a clear and unambiguous consequence of what is explicitly mentioned (see e.g. T 823/96, point 4.5 of the Reasons, T 590/07, point 2.4.3 of the Reasons).

3.2 Claim 1 of the main request has been amended in that composition claim 1 of the application as originally filed has been reformulated into a purpose-related composition claim (i.e. for dialysis on a patient in need thereof). Furthermore, the features that the dialysis is performed in a dialyser and in the absence of systemic administration of an anticoagulant have been added. The patients according to claim 1 of the main request include all patients in need of dialysis.

3.3 According to the opposition division, claim 1 of the main request found its basis on pages 3, 4 and 10 of the application as originally filed (see decision under appeal, point 18.2). No particular passages were mentioned in the contested decision. However, it is apparent from the minutes of the oral proceedings before the opposition division (see page 1, point 6) that lines 22 to 27 on page 3, lines 2 to 16 on page 4 and line 11 to 15 on page 10 were particularly relied on by the patent proprietor.

3.3.1 The board notes that the absence of systemic administration of an anticoagulant can be found in the passage on page 4, lines 2 to 16, in particular lines 6 to 8 and lines 9 to 11. Lines 6 to 8 read as follows: "Heparin or other anti-coagulant should not be delivered systemically to these patients because

retaining the patient's ability to clot blood is an important part of the healing process (emphasis added by the board)." The preceding sentence makes clear that "these patients" are post-operative patients with acute kidney failure. In lines 9 to 11 on page 4 it is explicitly stated that "with the high citrate dialysate of the present invention, a patient with acute kidney failure can undergo successful dialysis without systemic administration of anti-coagulant". That passage is followed by the statement that for a patient with acute kidney failure, the exposure to high citrate dialysate may have additional advantages.

The disclosure on page 4, lines 2 to 16 of the application as originally filed is therefore limited to a specific group of dialysis patients, namely to (post-operative) patients with acute kidney failure.

3.3.2 The passage on page 3, lines 22 to 27 of the application as originally filed is silent as to the systemic administration of an anti-coagulant. It merely states that a dialysate citrate concentration of 2.4 mEq/L and higher provides an anti-coagulation effect at the point of blood/dialysate interaction, i.e. the pore openings of the dialyser, but is not high enough to act as a systemic anti-coagulant.

3.3.3 The passage on page 10, lines 11 to 15 of the application as originally filed mentions particular groups of patients for whom the use of the high citrate dialysate according to the invention would be suitable, including patients with a risk of bleeding, an antibody to (intolerance to) heparin or chronic acidosis. The absence of systemic administration of an anti-coagulant is not explicitly mentioned in this context. Nor does the disclosure on page 10 necessarily imply that

systemic administration of an anti-coagulant is absent, let alone that it is absent in all patients in need of dialysis. On the contrary, it is part of the skilled person's common general knowledge that patients with a bleeding risk may receive heparin in a lower dose, according to specific schemes or in a particular form with a low risk of bleeding (see document R17, page 128, lines 38 to 40, page 133, penultimate line to page 134, line 6, page 134, lines 32 to 38). Patients with heparin intolerance may receive alternative anti-coagulants such as prostanoids (see R5, page 327, right-hand column, last paragraph to page 328, left-hand column, first paragraph; R17, page 134, lines 23 to 31). No reasons are apparent to the board as to why a patient having chronic acidosis need to avoid systemic administration of anti-coagulants.

3.4 Hence, in the board's judgement, none of the aforementioned passages provides a direct and unambiguous basis for the absence of systemic administration of an anti-coagulant in all dialysis patients.

3.5 Nor is such a feature directly and unambiguously derivable from any other passage on pages 3, 4 and 10 or any other part of the application as originally filed.

3.5.1 On page 5, lines 21 to 26 of the application as filed it is mentioned that a patient that is prone to undesirable clotting may receive dialysis without the need to receive an injection or other direct administration of an anti-coagulant. However, that statement is made in the context of a particular approach (see the formulation "Using this approach" at the beginning of that passage) and refers to the

preceding embodiment, namely the use of a dialysate with a high level of citrate without compensatory levels of calcium and/or magnesium (e.g. 2.5 and 1.0 mEq/L, respectively), which may be followed by an addition of calcium chloride.

3.5.2 On page 9, lines 19 to 28 of the application as filed, advantages of the localised anti-coagulant properties of citrate are mentioned. They include reducing or eliminating the need for the anti-coagulant heparin (see page 9, lines 27 to 28). This statement, in the board's judgement, cannot be equated to a direct and unambiguous disclosure of performing dialysis without systemic administration of an anti-coagulant in all dialysis patients, in particular taking into account the application as a whole, which discloses the absence of systemic administration only in particular circumstances (see points 3.3.1 and 3.5.1 above). Moreover, it is part of the common general knowledge of the person skilled in the art that dialysis is routinely performed with systemic administration of an anti-coagulant (such as heparin) to avoid the risk of clotting in the extracorporeal blood circuit in hemodialysed patients, except in specific cases, e.g. when the patient is actively bleeding (post-operative), has a high risk of bleeding or an intolerance to heparin (see document R5, page 326, right-hand column, second complete paragraph, page 328, left-hand column, lines 1 to 3 of the first complete paragraph; R17, page 121, lines 1 to 15, page 123, lines 27 to 30, page 130, lines 43 to 50). Hence, for the skilled reader the reference on page 9, lines 27 to 28, does not necessarily imply that systemic administration of an anti-coagulant should be absent in all groups of patients. Rather, taking into account the disclosure on page 4, lines 2 to 16 and on page 5, lines 21 to 26, of

the application as filed and his common general knowledge, he would understand that with the high citrate dialysate of the invention systemic administration of heparin can be eliminated in those patients which are particular at risk when given anti-coagulants such as heparin.

3.6 For the aforementioned reasons, the board concludes that performing dialysis in the absence of systemic administration of an anti-coagulant on any patient is technical information, which is not directly and unambiguously derivable from the application as originally filed, either explicitly or implicitly. The subject-matter of claim 1 of the main request therefore contravenes Article 123(2) EPC.

Auxiliary request ("Second amended claims")

4. Amendments

4.1 Claim 1 of the auxiliary request differs from claim 1 of the main request in that it further comprises selecting a patient in a heparin-free state and maintaining that patient in a heparin-free state while performing the dialysis on that patient.

4.2 This additional feature has a basis in claim 7 of the application as filed, which is directed to a method of performing heparin-free dialysis on heparin-free patients with a dialysate according to any of claims 1 to 4. However, neither claim 7 nor claims 1 to 4 contain the feature "in the absence of systemic administration of an anti-coagulant". Nor is there a clear and unambiguous disclosure in the description of the application as originally filed, which combines the absence of systemic administration of an anticoagulant

with the dialysis of heparin-free patients who are kept heparin-free during the dialysis.

4.3 As explained in point 3.3.1 above, page 4 of the application as filed discloses the absence of systemic administration of an anti-coagulant, including heparin, for patients with acute kidney failure. However, patients with acute kidney failure and patients who are heparin-free and are kept heparin-free during dialysis are not identical. The latter include patients with heparin intolerance, patients with an antibody to heparin, patients with a risk of bleeding and patients with chronic acidosis (see claims 4 to 7 of the auxiliary request). Those patient groups are, *inter alia*, disclosed on page 10, lines 11 to 15 of the application as filed. However, in that passage, the absence of systemic administration of an anti-coagulant is not disclosed. Nor is such an absence necessarily implied (see point 3.3.3 above).

4.4 It should also be noted that keeping a heparin-free patient heparin-free during dialysis is not synonymous to the absence of systemic administration of anti-coagulant. It simply means that heparin cannot be used as an anti-coagulant.

4.5 For the aforementioned reasons, the board concludes that claim 1 of the auxiliary request has no direct and unambiguous basis in the application as originally filed. Accordingly, this request must also be refused for non-compliance with Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe A. Lindner

Decision electronically authenticated