

Publication in the Official Journal ~~Yes~~ / No

File Number: T 79/91

Application No.: 85 903 547.9

Publication No.:

Title of invention: Hwmosialysis processes and hemodialysis solutions

Classification: B01D 13/00

D E C I S I O N
of 21 February 1992

Applicant: VEECH, Richard L.

Headword:

EPC Article 84

Keyword: Main Request - "Claims as a whole not clear and concise"
Auxiliary Request - "Remittal to Examining Division for further
examination"

Headnote



Case Number : T 79/91

D E C I S I O N
of the Technical Board of Appeal
of 21 February 1992

Appellant : VEECH, Richard L.
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Decision under appeal : Decision of Examining Division 031 of the
European Patent Office dated 7 August 1990
refusing European patent application
No. 85 903 547.9 pursuant to Article 97(1) EPC.

Composition of the Board :

Chairman : E. Turrini
Members : C. Black
C.V. Payraudeau

Summary of Facts and Submissions

- I. European patent application No. 85 903 547.9, based on international application PCT/US85/01205 (International Publication No. WO 86/00239) was refused by decision of the Examining Division.
- II. The refusal was based on Claims 1 to 35 received 8 February 1990, of which the independent Claims 1, 4, 11, 12, 13, 14, 19, 21, 22, 23, 27, 31 and 33 read as follows:

"1. A process for determining the composition of a hemodialysis solution, the process being characterised by comprising the steps of:

- (A) assigning approximate molar concentrations to the impermeant ions in the blood of a mammal to be hemodialyzed with the solution,
- (B) assigning to the solution a desired pH within the range of from about 5 to 9,
- (C) assigning respective concentrations to the permeant components desired in the blood after dialysis thereof,
- (D) entering each of the values obtained from said steps (A), (B) and (C) into the equations (2) hereinbefore disclosed, and
- (E) solving the equations to determine values for the respective concentrations of materials needed for the solution to achieve the desired blood composition in the blood after dialysis thereof with the solution.

4. A process for preparing a hemodialysis solution, the process being characterised by comprising the steps of:

- (A) assigning an approximate molar concentration to the total impermeant charged components, including albumin, in the blood of a mammal to be hemodialysed with the solution,
- (B) assigning to the solution a desired pH within the range from about 5 to 9,
- (C) assigning respective concentrations to the inorganic cations and inorganic anions desired in the blood after dialysis thereof,
- (D) entering each of the values obtained from said steps (A), (B) and (C) into the equations (2) hereinbefore disclosed,
- (E) solving the equations to determine values for the respective concentrations of materials needed for the solution to achieve the respective assigned concentrations in the blood after dialysis thereof with the solution, and
- (F) preparing an aqueous hemodialysis solution wherein the respective concentrations of the inorganic cations and the inorganic anions are approximately as determined in step (E).

11. A hemodialysis solution prepared by the process of claim 10 and containing:

Component	Quantity Range (millimoles per liter)
Total cations (mEq/L)	about 130 to about 170
(1) sodium ⁺	about 130 to about 155
(2) potassium ⁺	0 to about 6
(3) calcium 2 ⁺	0 to about 3
(4) magnesium ²⁺	0 to about 2
Total anions (mEq/L)	about 130 to about 170
(5) chloride-	about 84 to about 125
(6) bicarbonate-	0 to about 80
(7) l-lactate-/pyruvate-	0 to about 80
(8) d-betahydroxybutyrate-/ l-betahydroxybutyrate-	

acetoacetate-	0 to about 80
(9) sum (6+7+8)	about 25 to about 80
Total nonionics	0 to about 525
(10) carbon dioxide	0 to about 25
(11) osmotically active material	0 to about 500

and wherein:

- (A) the milliequivalent ratio of bicarbonate- to carbon dioxide is from about 0.1:1 to about 55:0.1
- (B) the milliequivalent ratio of l-lactate- to pyruvate- is from about 20:1 to about 1:1
- (C) the milliequivalent ratio of d-betahydroxybutyrate to acetoacetate- is from about 6:1 to about 0.5:1

12. A hemodialysis solution prepared by the process of any of claims 4 to 10, wherein the anion gap is filled by at least one near-equilibrium couple being bicarbonate and carbon dioxide, l-lactate and pyruvate, and/or d-betahydroxybuturate (sic) and acetoacetate.

13. A hemodialysis solution prepared by the process of claim 9 or 10, wherein the total concentration of all near-equilibrium couples is at least about 25 mM/l.

14. A process for estimating the concentrations of individual diffusible electrolytes present in an aqueous fluid containing at least one non-diffusible charged material after the fluid has been dialyzed with a solution containing known concentrations of diffusible charged material, the process being characterised by comprising the steps of:

- (A) determining the approximate molar concentration of the non-diffusible charged material present in the aqueous fluid,

- (B) entering the identities and concentrations of the diffusible charged material and the results from step (A) into the equations (2) hereinbefore disclosed, and
- (C) solving the equations (2) to determine the respective concentrations of individual diffusible electrolytes in the aqueous fluid containing the non-diffusible charged material after dialysis.

19. A process for hemodialyzing blood, wherein the renal function of a living mammal is replaced at least in part by dialysis, portions of the blood of the mammal are continuously passed over one face of a dialysis membrane while the opposed face of the membrane is contacted with a dialysis fluid, thereby to achieve a change in the chemical composition of the mammal's body fluids and the dialysis fluid contains dissolved therein at least one permeant ion found in the mammal's blood, characterised in that the concentration of the permeant ion(s) in the dialysis fluid is continuously varied while carrying out the hemodialysis, the rate of change of the continuous variation being such that the time interval during the hemodialysis from the start thereof required for the initial concentration of blood electrolytes present in the plasma of the blood of the mammal to change to a value which is about half-way between the anticipated final concentration of blood electrolytes at the termination of the hemodialysis and the initial concentration is about one-half of the total time interval anticipated for the duration of the hemodialysis.

21. A hemodialysis delivery apparatus which delivers hemodialysis fluid to a hemodialyzer apparatus (32; 130) and which comprises:

- (a) dialysis fluid supply pump means (23),

- (b) dialysis fluid supply pressure regulating means,
- (c) dialysis fluid supply temperature regulating means (31),
- (d) dialysis fluid supply flow-regulating means (34; 122),
- (e) dialysis fluid supply means (21,22,24,27,28; 100,101,102,103,104,105), and
- (f) conduit means (25,29; 124) interconnecting the pump means, regulating means and supply means, characterised in that the supply means incorporates means for continuously varying the composition of the dialysis fluid from an initial composition to a final composition.

22. A hemodialysis delivery apparatus which delivers hemodialysis fluid to a hemodialyzer apparatus (32; 130) and which comprises:

- (a) dialysis fluid supply pump means (23),
- (b) dialysis fluid supply pressure regulating means,
- (c) dialysis fluid supply temperature regulating means (31),
- (d) dialysis fluid supply flow-regulating means (34; 122),
- (e) dialysis fluid supply means (21,22,24,27,28; 100,101,102,103,104,105), and
- (f) conduit means (25,29; 124) interconnecting the pump means, regulating means and supply means, characterised in that the apparatus includes carbon dioxide mixing means (115,116,117,120,121,124,125).

23. A process for dialyzing through a dialysis membrane a dialyzable fluid which has dispersed and/or dissolved therein a non-permeant charged material, characterised in that the ionic composition of the dialyzable fluid is controlled by regulating the ionic

composition of the dialyzing fluid being used for dialyzing the dialyzable fluid in such a way as to determine the concentration of permeant ions in the dialyzable fluid.

27. A process for estimating the composition of a dialyzable fluid which contains impermeant ions after the fluid has been dialyzed with a dialyzing fluid of specified composition, the processing being characterised by comprising the steps of:

- (A) determining the charge and the concentration of the impermeant ions in the dialyzable fluid, and
- (B) calculating the composition of the dialyzable fluid after dialysis thereof with the dialyzing fluid.

31. A process for determining the ionic composition of a dialyzing fluid for dialyzing a dialyzable fluid containing at least one impermeant ion, thereby to change the concentration of permeant ions in the dialyzable fluid to a predetermined concentration, the process being characterised by comprising the steps of:

- (A) selecting a final ionic composition for the dialyzable fluid after dialysis,
- (B) determining the charge and concentration of the impermeant ion in the dialyzable fluid, and
- (C) calculating using equations (2) hereinbefore disclosed the composition of the dialyzing fluid.

33. A dialysis process in which a dialyzable fluid from a reservoir is dialyzed against a dialyzing fluid, characterised in that the composition of the dialyzing fluid during said dialysis is varied in a predetermined

manner to produce a predetermined rate of change in the reservoir."

The claims to which Claims 11, 12 and 13 refer, other than Claim 4, are dependent claims referring back to Claim 4.

III. The reason for the refusal was that the application did not meet the requirements of Article 84 EPC in that the claims considered as a whole were not clear and concise. In paragraph 3 of the Reasons for the Decision, the Examining Division added the following:

"although not forming part of the reasons for this decision the following points would also bar grant of the present application:-

- (i) the references to "the equations (2) hereinbefore disclosed" offends against Rule 29(6).
- (ii) Claims 19 and 20 are directed to methods of medical treatment Article 52(4).
- (iii) At least apparatus Claims 21, 22, differing only in their characterising feature, are not directed to the same invention, Article 82."

IV. An appeal was lodged against this decision. In the Statement of Grounds for the Appeal, the Appellant (Applicant) requested in effect the following:

- (1) The decision refusing the application to be set aside and the application remitted to the Examining Division for further examination as to its patentability on the basis of the claims considered in the decision (main request).

- (2) As (1) on the basis of a replacement set of claims filed 17 December 1990 (auxiliary request) of which Claims 1 and 2 (the only independent claims) read as follows:

1. A hemodialysis delivery apparatus which delivers hemodialysis fluid to a hemodialyzer apparatus (32; 130) and which comprises:

- (a) dialysis fluid supply pump means (23),
- (b) dialysis fluid supply pressure regulating means,
- (c) dialysis fluid supply temperature regulating means (31),
- (d) dialysis fluid supply flow-regulating means (34; 122),
- (e) dialysis fluid supply means (21,22,24,27,28; 100,101,102,103,104,105), and
- (f) conduit means (25,29; 124) interconnecting the pump means, regulating means and supply means,

characterised in that the supply means incorporates means for continuously varying the composition of the dialysis fluid from an initial composition to a final composition.

2. A process for dialyzing through a dialysis membrane a dialyzable fluid which has dispersed and/or dissolved therein a non-permeant charged material, characterised in that the ionic composition of the dialyzable fluid is controlled by regulating the ionic composition of the dialyzing fluid being used for dialyzing the dialyzable fluid in such a way as to determine the concentration of permeant ions in the dialyzable fluid.

(3) Refund of the appeal fee.

(4) Oral proceedings to be appointed if neither the main nor the auxiliary request appear allowable.

In respect of the auxiliary request, the Appellant added that this request was without prejudice to his right to file one or more divisional applications within the appropriate time limit.

V. In support of these requests the Appellant argues in substance as follows:

The number of claims according to the main request is the minimum necessary to provide the overall scope of protection which the Applicant seeks and any reduction in number will reduce the overall scope and disadvantage the Applicant. In any case it is by no means unknown for European patents to be granted containing several independent claims in the same category, for example EP-B1-0 086 633.

The claims according to the auxiliary request should be allowable in that Claim 2 is an independent claim for a process and Claim 1 an independent claims for an apparatus specifically designed for carrying out the process of Claim 2.

As regards the request for reimbursement of the appeal fee, this is justified in the first place on the ground that interlocutory revision of the decision refusing the application is appropriate.

Further a substantial procedural violation has occurred in that the application was refused after only one official action which gave no warning that refusal was

contemplated, in contravention of the Guidelines for Examination in the European Patent Office, C-VI 4.3. The Applicant's response to the said official action constituted a bona fide attempt to meet the objection raised in that the number of independent claims had been reduced from thirteen to ten.

Moreover, objection that the claims lacked unity of invention was raised for the first time in the decision refusing the application.

Reasons for the Decision

1. The appeal is admissible.
2. Main Request
 - 2.1 A point which requires clarification first of all is the number of independent claims in the set according to the main request. The Appellant considers that there are ten, whereas the Examining Division listed thirteen. The Board agrees with the Examining Division because Claims 11 to 13, although referring back to Claim 10 at least, are independent claims. However it is of little significance as regards the result of the appeal whether the number is ten or thirteen. In any case the present wording at least of Claims 12 and 13 could be considered as adding conciseness to the claims as a whole.
 - 2.2 In refusing the application on the ground that the claims as a whole were not clear and concise, this objection having been raised in the single communication during the examination proceedings, the Examining Division was following established practice in the EPO - see the Guidelines C-III 4.1 and C-III 5.1 as regards clarity and

conciseness respectively. It is clear that this objection can arise even if individual claims are clear and concise in themselves, and that the lack of clarity of the claims as a whole arises from the lack of conciseness.

In the present case, what the Applicant considers according to his main request to be the invention has been set out in at least ten independent claims of different, though to a greater or lesser degree overlapping, scope. This presentation makes it difficult, if at all possible, to determine the matter for which protection is sought and places an undue burden on others seeking to establish the extent of the monopoly.

- 2.3 The Appellant drew attention to EP-B-0 086 633 as an example of a patent granted with a plurality of independent claims. Prima facie these claims appear open to the same objection, even though there are somewhat fewer independent claims (six) than in the application in suit and these are all in the same category. However each case has to be judged on the adduced facts and arguments and it may be that convincing reasons were presented as to why the claims of EP-B-0 086 633 could be considered allowable. In the present case the mere statement that the number of claims is the minimum necessary to provide the overall scope of protection which the Applicant seeks is not a convincing argument. Accordingly the main request cannot be allowed.
- 2.4 The finding that the claims as a whole are not clear and concise is wholly independent of any consideration as to whether the claims meet the requirement of unity of invention.
- 2.5 The Appellant has contended that the Examining Division was guilty of a substantial procedural violation in

refusing the application after only one communication, because this constituted a contravention of the Guidelines C-VI 4.3. As is explained in decision T 42/84 of Technical Board of Appeal 3.4.1 (OJ EPO 1988, 251), the Guidelines do not have the binding authority of a legal text, so that a failure by the Examining Division to follow them is not to be considered as a procedural violation within the meaning of Rule 67 EPC unless it also constitutes a violation of a rule or principle of procedure governed by an article of the EPC or one of the implementing Regulations (see paragraph 9 of the Reasons for the Decision). In the present case this requires investigation as to whether Articles 96(2) and 113(1) EPC have been contravened and in this connection, paragraphs 12 and 13 of decision T 162/82 of Technical Board of Appeal 3.5.1 are pertinent and read as follows:

"12. In the Board's opinion, the expression "as often as necessary" in Article 96(2) EPC indicates that the Examining Division has a discretion which has to be exercised objectively in the light of the circumstances of each case. In particular, it has to be interpreted as meaning that further invitations to file observations after the first one are required if there is a reasonable prospect that further discussion with the applicant could lead to reconciling conflicting opinions of the applicant and the Examining Division as to the allowability of the application or to the submission of amendments which might meet the objections raised. Of course, this Article does not exclude communication with the applicant in other circumstances but it relieves the Examining Division of any obligation to send communications which on a reasonable, objective basis could be considered superfluous. The interests of orderly and economic examining procedures may preclude the sending of more than

one communication where this would not appear to be likely to lead to a positive result.

13. The Board has previously held that neither Article 113(1) nor Article 96(2) EPC requires that the applicant be given a repeated opportunity to comment on the argumentation of the Examining Division so long as the decisive objection against the grant of a patent remains the same (case T 161/82, OJ EPO 1984, 55)."

In the present case the Examining Division found that in response to the single communication, the amended claims contained the same number (thirteen) of independent claims as before. Moreover the response did not contain reasons why the number of claims was necessary, but the mere statement that it was the minimum necessary to provide the overall scope of protection which the Applicant seeks. Accordingly the Examining Division's exercise of its discretion in refusing the application after one communication is not unreasonable and there is no contravention of Article 96(2).

Moreover the decisive objection on which the decision was based remained the same as that set out in the single communication, so that Article 113(1) is not contravened either.

The Appellant further objects that the question of lack of unity was brought up for the first time in the decision refusing the application. Here again there is no substantial procedural violation because it is clear from the wording of the decision that refusal of the application was based solely on the objection under Article 84 EPC, the decision in effect ending with paragraph 2 of the reasons therefor. The additional paragraph 3 then begins "although nor forming part of the

reasons for this decision ...". The Examining Division presumably felt that it would be useful to mention other apparent defects in the application so that the Applicant could take these into account in any subsequent proceedings. It is clear moreover that these are not exhaustive and that Claims 19 and 20 were merely selected as clear examples of two claims lacking unity of invention with each other. That the matters raised in the said paragraph 3 were not dealt with in the single communication is not moreover seen as being inconsistent with the Guidelines C-VI 3.3 (first letter should cover all objections etc.). The defect giving rise to the main objection is such as to make efficient examination impossible, and in such a situation it is proper to defer the complete examination.

3. Auxiliary Request

The claims according to the auxiliary request contain only two independent claims which are in different categories. The objection that the claims as a whole are not clear and concise therefore does not arise and for this reason the auxiliary request can be allowed.

4. Reimbursement of appeal fees

4.1 This has to be rejected because in the present case neither of the conditions set out in Rule 67 apply. Firstly the appeal does not succeed to the extent that the main request has been found not to be allowable (paragraphs 2.2 and 2.3 above). Further there has been no substantial procedural violation (paragraph 2.5 above).

4.2 The Appellant put forward, as another reason for reimbursement of the appeal fees, that the present case was an appropriate one for interlocutory revision. The

Board cannot agree with this view. In the first place the Examining Division was presented with a main request relating to the same claims as had formed the basis of the decision refusing the application, and therefore could not reasonably rectify its decision. Secondly reimbursement of appeal fees is not an automatic consequence of interlocutory revision. The proper interpretation of Rule 67 EPC is that also in the case of interlocutory revision, there has to have been a substantial procedural error.

5. Since the Appellant's auxiliary request has been allowed, there was no need to appoint oral proceedings (see paragraph IV(4) above).

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Examining Division for further examination on the basis of Claims 1 to 5 according to the Appellant's auxiliary request.
3. The request for reimbursement of the appeal fees is rejected.

The Registrar:

The Chairman:

P. Martorana

E. Turrini