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Datasheet for the decision of 15 October 2009

Case Number: T 0867/05 - 3.3.07

Application Number: 96304795.6

Publication Number: 0750936

IPC: B01D 67/00

Language of the proceedings: EN

Title of invention:
Permselective membranes and methods for their production

Patent Proprietors:
TORAY INDUSTRIES, INC.

Opponents:
Fresenius Medical Care AG

Headword:
-

Relevant legal provisions:
EPC Art. 123(2)(3)
EPC R. 80

Relevant legal provisions (EPC 1973):
EPC Art. 84, 111(1)

Keyword:
"Main Request, 1st and 2nd Auxiliary Requests - Amendments - allowable (no) - Clarity (no) - added subject-matter (yes) - extension of protection (yes) - (*Aliud*)"
"3rd Auxiliary Request - Amendments - allowable (no) - Clarity (no)"
"4th Auxiliary Request - Admissible (yes) - Amendments - allowable (yes) - Remittal (yes)"
"Referral to the Enlarged Board (no)"

Decisions cited:
T 0528/93, T 0168/99

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0867/05 **-** 3.3.07

D E C I S I O N
of the Technical Board of Appeal 3.3.07
of 15 October 2009

Appellants: (Opponents)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 3 June 2005 concerning maintenance of European patent No. 0750936 in amended form.

Composition of the Board:

Chairman: S. Perryman
Members: G. Santavicca
D. Semino

Summary of Facts and Submissions

I. The appeal lies from the interlocutory decision of the Opposition Division maintaining European patent 0 750 936 (application N° 96 304 795.6) on the basis of Claims 1 to 10 of Subsidiary Request 1C submitted during the oral proceedings held on 27 January 2005.

II. The patent as granted comprised 19 claims, Claims 1, 10, 12, 13, 18 and 19 reading as follows:

"1. A membrane material comprising a polysulfone as a hydrophobic polymer and a polyvinyl pyrrolidone as a hydrophilic polymer, wherein the polyvinyl pyrrolidone is present in the membrane in an amount of 3 to 15% by weight of the total weight of the polysulfone and the polyvinyl pyrrolidone, characterised in that the hydrophilic polymer consists of 10-50 wt.%, based on the total hydrophilic polymer, of a low molecular weight component having a molecular weight, as measured by gel permeation chromatography, less than 100,000 and 90-50 wt.%, based on the total hydrophilic polymer, of a high molecular weight component having a molecular weight, as measured by gel permeation chromatography, of 100,000 or more."

"10. Use of a membrane material according to any preceding claim in an in vitro permselective filtration process."

"12. A permselective material, for use in dialysis, comprising a membrane according to any one of claims 1-9."

"13. A method of producing a polymeric membrane as claimed in any one of claims 1 to 9, the method comprising forming a solution comprising a polysulfone as a hydrophobic polymer, a polyvinyl pyrrolidone as a hydrophilic polymer and a solvent, the hydrophilic polymer consisting of at least two components having different respective molecular weights, a low molecular weight said component having a weight average molecular weight less than 100,000 and a high molecular weight said component having a molecular weight of at least 100,000, and the solvent being capable of dissolving each of the hydrophobic polymer and the hydrophilic polymer, forming the said solution into a membrane and removing the solvent from the membrane to obtain the polymeric membrane."

"18. A method according to any one of claims 13 to 17, which includes the subsequent step of subjecting the membrane to an insolubilization step."

"19. A method according to claim 18, wherein the insolubilization is carried out by subjecting the membrane material to cross linking by at least one method selected from γ—ray and electron beam irradiation, heating or chemical treatment.".

III. The patent in its entirety was opposed on the grounds that its subject-matter lacked novelty and an inventive step (Article 100(a) EPC) and its invention was not sufficiently disclosed (Article 100(b) EPC).

IV. Claim 1 of Subsidiary Request 1C underlying the decision under appeal was the only independent claim

and read as follows (compared to Claim 1 as granted, additions are shown in bold):

"1. **An artificial kidney in which there is used** a membrane material comprising a polysulfone as a hydrophobic polymer and a polyvinyl pyrrolidone as a hydrophilic polymer, wherein the polyvinyl pyrrolidone is present in the membrane in an amount of 3 to 15% by weight of the total weight of the polysulfone and the polyvinyl pyrrolidone, characterised in that the hydrophilic polymer consists of 10-50 wt.%, based on the total hydrophilic polymer, of a low molecular weight component having a molecular weight, as measured by gel permeation chromatography, less than 100,000 and 90-50 wt.%, based on the total hydrophilic polymer, of a high molecular weight component having a molecular weight, as measured by gel permeation chromatography, of 100,000 or more."

V. In the decision under appeal, the Opposition Division came to the following conclusions:

(a) the Main Request and Subsidiary Request 1B, both filed at the oral proceedings on 27 January 2005 (Subsidiary Request 1A was withdrawn), were not allowable, because Claim 4 of the Main Request contravened the requirements of Article 123(3) EPC and the subject-matter of Claim 11 of Subsidiary Request 1B lacked novelty over D2 (JP-A-63 097 205) (in the form of its English translation);

(b) the patent amended on the basis of the claims of Subsidiary Request 1C complied with the requirements of the EPC, in particular with Articles 123(2)(3), 84, 83, 54 and 56 EPC.

VI. In their statement setting out the grounds of appeal, Appellants 01 (opponents) enclosed copies of the following documents:

D16: H.J. Gurland (Ed.), Uremia Therapy, Springer Verlag, 1987, pages 28 to 31;

D17: Römpp Chemie Lexikon, 9th Edition, Volume 6, keyword "*Vernetzung*", 1992;

D18: L. W. Henderson, "*Biophysics of Ultrafiltration and Hemofiltration*" in Replacement of Renal Function by Dialysis, edited by W. Drukker et al, 2nd edition, Martinus Nijhoff Publishers, Boston, 1983, pages 242 to 264; and,

D19: J.C. Van Stone and J.T. Daugirdas, "*Physiologic principles*", in Handbook of Dialysis, edited by J.T. Daugirdas et al, 2nd edition, 1994, pages 13 to 29.

Then, by letter dated 27 October 2006, in response to a letter of the appellants proprietors dated 27 February 2006, the appellants opponents submitted copies of further documents as follows:

D20: H. Chmiel et al., Abstract of "*Membranen in der medizinischen Verfahrenstechnik*", Chemie Ingenieur Technik, Volume 55, 4th issue, Pages 282-292;

D21: Copy taken on 17 October 2006 from the website http://plant-tc.coafes.umn.edu/listserv/2001/log0102/msg00033.html;

D22: EP-A-0 103 816;

D23: US-4 345 999; and,

D24: JP-A-01 032 868 (Patent Abstracts of Japan).

VII. In their statement setting out the grounds of appeal, Appellants 02 (proprietors) enclosed a Main Request, containing Claims 1 to 10 of Subsidiary Request 1C

underlying the decision under appeal and method Claims 11 to 16, and Subsidiary Requests 1 to 12. Then, by letter dated 27 February 2006, Appellants 02 submitted copy of an English translation of D10 (EP-A-0-550 798) as well as copies of a new Main Request and two additional subsidiary requests to be numbered 8 and 12, bringing the total number of the subsidiary requests to 15.

VIII. The Board, in a communication in preparation for the oral proceedings, indicated the points to be discussed, in particular whether or not the claims containing the amendment "artificial kidney" complied with the requirements of Articles 84, 123(2)(3) and Rule 80 EPC.

IX. In response to the communication of the Board:

(a) Appellants 01 (opponents), in their letter of 8 September 2009, enclosed copies of further documents:

D25a: Enka AG, Development and Properties of Cuprophan(R) Membranes, Part 1 of the presentation at the symposium "Biocompatibilité des Membranes en Hémodialyse", held in Grenoble (FR) in November 1984, printed on April 1985;

D25b: Homepage of Membrana (htpp://www.membrana.de/haemodialysis/center.htm), Membranes for Haemodialysis, 02.09.2009;

D25c: Dieter Schleipfer, Dialysetechnik, 4th revised edition, Bionic, Gesellschaft für angewandte Medizintechnik m.b.H & Co KG, 1988, pages 58, 60, 62 and 64;

D25d: N. A. Hoenich and D.N.S. Kerr, Dialysers, in Replacement of Renal Function by Dialysis, edited by W. Druckker et al. second revised and enlarged edition, Martinus Nijhoff Publishers, Boston, 1983, pages 106, 108, 109, 114, 136;

D25e: Comparison Dialysers and Filters, data taken from manufacturer's brochures, March 1995.

Then, by letter dated 5 October 2009, the appellants opponents submitted their arguments on the latest requests of the appellants proprietors.

(b) The appellants proprietors, with their letter dated 11 September 2009, submitted:

- a Declaration by Mr Kozawa dated 11 September 2009;
- an Experimental Report (which had been placed on the public file of the patent in suit during the examination proceedings); and,
- fresh Main Request and Auxiliary Requests 1 to 17.

By letter dated 14 October 2009, the appellants proprietors submitted:

- a copy of D2 with highlighted passages of Examples 2 to 6, to show that PVP K90 had been used;
- a certified translation of the final paragraph of D2; and,
- copies of US-A-4 720 343 and US-A-4 906 375, corresponding respectively to D1 (EP-A-0 082 433) and D9 (EP-A-0 168 783).

Reference was also made to decisions T 325/95 of 18 November 1997 and T 579/01 of 30 June 2004 (both not published in the OJ EPO).

X. Oral proceedings were held on 15 October 2009. The appellants proprietors withdrew the 4th to 6th Auxiliary Requests filed with letter dated 11 September 2009 and submitted a fresh 4th Auxiliary Request. At the end of the oral proceedings, it was announced that the decision would be given in writing.

XI. The claims on which the present decision is based, namely Claim 1 of each of the Main Request and the 1st to 3rd Auxiliary Requests filed with letter dated 11 September 2009 as well as those of the 4th Auxiliary Request filed at the oral proceedings on 15 October 2009, read as follows (compared to the respective claims as granted, additions are shown in bold, deletions in strike-through):

Main Request

Claim 1 is identical to Claim 1 of Subsidiary Request 1C underlying the decision under appeal (Point IV, *supra*).

1st Auxiliary Request

"1. **An artificial kidney in which there is used** a membrane material comprising a polysulfone as a hydrophobic polymer and a polyvinyl pyrrolidone as a hydrophilic polymer, wherein the polyvinyl pyrrolidone is present in the membrane in an amount of 3 to 15% by

weight of the total weight of the polysulfone and the polyvinyl pyrrolidone, characterised in that the hydrophilic polymer consists of 10-50 wt.%, based on the total hydrophilic polymer, of a low molecular weight component having a molecular weight, as measured by gel permeation chromatography, less than 100,000 and 90-50 wt.%, based on the total hydrophilic polymer, of a high molecular weight component having a molecular weight, as measured by gel permeation chromatography, of 100,000 or more, **and wherein the membrane material has an overall mass transfer coefficient (K_o), for a Stoke's radius of at least 30 Å, as determined by a diffusion test using dextran, of at least 0.0025 cm/mm or more and a permeability to albumin of 4% or less**."

2nd Auxiliary Request

Claim 1 is identical to Claim 1 of the 1st Auxiliary Request.

3rd Auxiliary Request

"1. A membrane material **for use in an artificial kidney, the membrane material** comprising a polysulfone as a hydrophobic polymer and a polyvinyl pyrrolidone as a hydrophilic polymer, wherein the polyvinyl pyrrolidone is present in the membrane in an amount of 3 to 15% by weight of the total weight of the polysulfone and the polyvinyl pyrrolidone, characterised in that the hydrophilic polymer consists of 10-50 wt.%, based on the total hydrophilic polymer, of a low molecular weight component having a molecular weight, as measured by gel permeation chromatography, less than 100,000 and 90-50 wt.%, based on the total hydrophilic polymer, of

a high molecular weight component having a molecular weight, as measured by gel permeation chromatography, of 100,000 or more."

4th Auxiliary Request

"1. A membrane material comprising a polysulfone as a hydrophobic polymer and a polyvinyl pyrrolidone as a hydrophilic polymer, wherein the polyvinyl pyrrolidone is present in the membrane in an amount of 3 to 15% by weight of the total weight of the polysulfone and the polyvinyl pyrrolidone, characterised in that the hydrophilic polymer consists of 10-50 wt.%, based on the total hydrophilic polymer, of a low molecular weight component having a molecular weight, as measured by gel permeation chromatography, less than 100,000 and 90-50 wt.%, based on the total hydrophilic polymer, of a high molecular weight component having a molecular weight, as measured by gel permeation chromatography, of 100,000 or more, **and wherein the membrane material has an overall mass transfer coefficient (K_o), for a Stoke's radius of at least 30 Å, as determined by a diffusion test using dextran, of at least 0.0025 cm/mm or more and a permeability to albumin of 4% or less**.".

"1**2**~~3~~. A method of producing a polymeric membrane as claimed in any one of claims 1 to **8**~~9~~, the method comprising forming a solution comprising a polysulfone as a hydrophobic polymer, a polyvinyl pyrrolidone as a hydrophilic polymer and a solvent, the hydrophilic polymer consisting of at least two components having different respective molecular weights, a low molecular weight said component having a weight average molecular weight less than 100,000 and a high molecular weight

said component having a molecular weight of at least 100,000, and the solvent being capable of dissolving each of the hydrophobic polymer and the hydrophilic polymer, forming the said solution into a membrane and removing the solvent from the membrane to obtain the polymeric membrane."

"1~~8~~**7**. A method according to any one of claims 1**2**~~3~~ to 1**6**~~7~~, which includes the subsequent step of subjecting the membrane to an insolubilization step ~~19. A method according to claim 18,~~ wherein the insolubilization is carried out by subjecting the membrane material to cross linking by ~~at least one method selected from~~ γ-ray ~~and electron beam~~ irradiation, ~~heating or chemical treatment~~.".

XII. The appellants opponents essentially argued as follows:

Main, 1st and 2nd Auxiliary Requests

Amendments

Claim 1 contained the amendment "artificial kidney".

Clarity

The term "artificial kidney" did not make it clear how an artificial kidney was made up, i.e. what physical entity fell under that definition, and thus was unclear.

Extension beyond the application as filed

Since the application as filed did not disclose an artificial

kidney had no basis in the application as originally filed (Article 123(2) EPC).

Extension of the protection

The patent as granted contained only claims concerning a membrane, its manufacture and a particular use thereof. The amended claims in opposition proceedings instead concerned an artificial kidney, which was not defined in any of the claims as granted and was a different subject-matter. Hence, the change from membrane to artificial kidney shifted the protection to a physical entity foreign to the protection conferred by the claims as granted (***aliud***), thus contravening Article 123(3) EPC.

The principle behind Article 123(3) EPC implied that, after the grant of the patent, the proprietors could not revert to subject-matter not claimed. Broadening of the granted claims was forbidden even in cases in which the amended subject-matter was disclosed originally (G 1/93, OJ EPO 1994, 541). An act that did not infringe the granted subject-matter was not to become an infringement because of the amendments made in opposition proceedings.

It was apparent from D20 that the membrane was an essential part of an artificial kidney, and from documents D25, concerning Cuprophan(R) membranes, that membranes and artificial kidneys were manufactured in different industries, by different manufacturers, implying that artificial kidney was not a synonym for membrane and that membranes and artificial kidneys related to different industries. In view of the

amendments made, a manufacturer of an artificial kidney, who purchased the membrane and used it in its artificial kidney, thus exhausting the rights of the patent by the purchase of the membrane and not infringing any of the claims as granted by the act of producing artificial kidneys, would now infringe the amended claims.

The determination of the protection conferred pertained to the national courts, not to the Opposition Division, in particular in view of the equivalents. However, to establish compliance with Article 123(3) EPC, a test according to Article 69 EPC and its protocol should be carried out to show that the protection conferred by the amended claims should be equal or less than that conferred by the patent as granted.

G 2/88 (OJ 1990, 93), concerning a second non medical use of a product and allowing a change of category from a product to the use of the product, i.e. restricting the protection conferred, was not relevant to the present case, in which a physical entity was changed to a completely different physical entity, i.e. an aliud.

The most relevant decision to the present case was T 352/04 of 11 October 2007, in which a composition of matter as granted was changed to a composition of matter in a mechanical sprayer, which encompassed also the apparatus and protected more subject-matter than that as granted, thus violating the requirements of Article 123(3) EPC. This situation was similar to the present situation, in which a membrane material had been changed to an artificial kidney comprising the membrane material.

Therefore, all the claims concerning an "artificial kidney" were not in compliance with Article 123(3) EPC.

Appropriateness

Since the term "artificial kidney" was not clear, the amendment in Claim 1 was not appropriate for overcoming any of the invoked grounds of opposition.

3rd Auxiliary Request

The amendment "for use in an artificial kidney" did not provide any of the invoked limitations for the membrane material, such as water permeability and clearance factor, so that Claim 1 was not clear and the 3rd Auxiliary Request was not allowable.

4th Auxiliary Request

Procedural questions

At the oral proceedings before the Opposition Division, the proprietors had acknowledged that the then claimed membrane was known from D2, so that the claims were amended to define an artificial kidney. All of the requests containing claims directed to membranes were withdrawn. A decision was made on the claims concerning artificial kidneys. Hence, claims directed to membranes as the present ones had not been dealt with, so that the proprietors were not adversely affected by the decision under appeal as far as a membrane material was concerned. If the artificial kidney claims were not allowable, the proprietors could only defend the

process claims. Consequently, it was not admissible to go back to the membrane claims.

In that respect, the opponents referred to T 528/93 of 23 October 1996, acknowledged in the Case Law of the Boards of Appeal of the EPO, 5th edition 2006 (VI.J.3.2.2(b)), and requested that a question of law be referred to the Enlarged Board of Appeal of the EPO, as follows:
"To what extent are patent proprietors in appeal proceedings entitled to revert to a claim request which they abandoned before the Opposition Division?".

Amendments

No objection under Article 84 and 123 EPC was raised against the amendments.

Remittal

Since novelty and inventive step had not been dealt with by the Opposition Division, if the 4th Auxiliary Request was admissible and formally allowable, the case should be remitted to the Opposition Division for further prosecution.

XIII. The appellants proprietors essentially (counter) argued as follows:

Main, 1st and 2nd Auxiliary Requests

Amendments

Compared to Claim 1 as granted, concerning a "membrane material", Claim 1 of the Main, 1st and 2nd Auxiliary requests had been amended to an "artificial kidney, in which there is used a membrane material".

Clarity

The term artificial kidney, mentioned in several documents cited and in the prior art acknowledged in the patent in suit, was known. The skilled person understood under that term any article being capable to mimic the function of a human kidney, which did not consist only of a membrane but comprised a module in which membranes were packed as well further components for using the article as an artificial kidney, so that also its function and performance were known. Therefore, the term artificial kidney was clear.

Extension of the content of the application as filed

The amended claims to an artificial kidney, in particular Claim 1, were based on the application as originally filed, which in particular mentioned the suitability of the membrane to mimic the function of a human kidney in several instances (e.g. page 4, lines 28-30, of the patent in suit), implying its use in an artificial kidney. Reference was also made to the following paragraphs of the patent in suit: 0002, 0004, 0009, 0019, 0021, 0027 to 0033. Hence, the content of the application as filed had not been extended by the amendment "artificial kidney".

Extension of the protection conferred by the claims as granted

It was established EPO practice that a granted claim to a particular component product which might form part of a larger product could be amended so as to be directed to the larger product comprising the component product without offending Article 123(3) EPC, as this represented a narrowing in protection.

A distinction should be drawn between the protection conferred by the claims as granted and the rights which were conferred by that protection. In fact, the rights conferred were not mentioned in Article 123(3) EPC but in Article 64(1) EPC, as a matter for the law of the contracting states. Hence, neither infringement nor any doctrine of exhaustion of the rights conferred were applicable to the present case, in which it only had to established whether or not the protection conferred had been extended by the amendment "artificial kidney".

As regards the protection conferred, with reference to Article 69 EPC and its protocol the test to be applied consisted of three steps as follows: determination of the extent of protection conferred by the totality of the claims as granted by considering their terms, their categories and their technical features, then, determination of the protection conferred by the amended claims and, finally, comparison of the two extents to see whether the protection conferred by the amended claims was within the protection conferred by the claims as granted. All this was in compliance with G 2/88 (*supra*).

In the present case, concepts such as cut off at grant or different manufacturing industries were not relevant. What had been done was simply the inclusion of

something to limit the subject-matter as granted. Even by considering the doctrine of exhaustion of rights, there was no change of protection.

On application of the principles of G 2/88 (*supra*) to the present case, it was apparent that since the membrane material of the claims as granted and the artificial kidney of the amended claims were both physical entities ("physical entity" encompassed products such as a membrane material and apparatuses such as an artificial kidney), no change of category had taken place.

The amended claims were directed to a physical entity containing more features, i.e. which was more limited, than the physical entity as granted. It was generally acknowledged that the protection conferred upon a physical entity was absolute and covered the physical entity in any possible context. G 1/93 (*supra*) was not conflicting with G 2/88 (*supra*) and aimed at preventing broadening of the claims. In the present case, the scope of Claim 1 had been narrowed.

In T 325/95 (*supra*), it was decided that the protection conferred by a claim in the sense of Article 123(2) EPC was defined by the terms of the claims and was not dependent on the validity of the claim.

The Board, in T 352/04 (*supra*), correctly decided that the amended claims contained more subject-matter than the granted claims, leading to an extension of the protection conferred. The situation however was different from that of the present case.

Instead T 579/91 (*supra*) dealt with a situation which was similar to the present, in which it was acknowledged that the protection conferred by a claim directed to a cell in a plant extended to the plant containing that cell, so that a change from a claim to a cell in a plant to a claim to a plant containing the cell did not offend Article 123(3) EPC.

Therefore, the protection conferred by the claims as granted had not been extended by the amended claims directed to an artificial kidney.

Appropriateness

The amendment "artificial kidney" aimed at overcoming the grounds of opposition lack of novelty and of an inventive step.

3rd Auxiliary Request

Claim 1 of 3rd Auxiliary Request was directed to a membrane material for use in an artificial kidney. The feature "for use in an artificial kidney" added further limitations to those resulting from the structural features relating to the distribution of polyvinylpyrrolidone (PVP), so that the scope of claim 1 as granted was limited to membranes having properties such as suitable water permeability for artificial kidneys. The membranes of D2 had extremely high or too high water permeability and were not suitable for artificial kidneys, so that the amendment aimed at overcoming a ground of opposition.

4th Auxiliary Request

Procedural questions

Since the opponents had attacked the claims of Subsidiary Request 1C found allowable by the Opposition Division, the proprietors were free to find suitable amendments to address the objections of the opponents and to select an appropriate set of claims for defending the patent in suit. They were thus entitled to have these new claims discussed in the appeal proceedings.

The question of being adversely affected or not concerned the admissibility of the appeal. In the present case, the proprietors, who had had a request refused, were adversely affected. During the oral proceedings before the Opposition Division it was indicated that the then claimed membrane lacked novelty over the membrane of D2, so that the claims were restricted to an artificial kidney, without any statement of abandonment but simply to get the requests thought to be allowable by the Opposition Division. Hence, the proprietors were entitled to revert to the broader claims directed to the membrane if the decision on the artificial kidney were reversed.

Decision T 0528/93 (***supra***) concerning virtually identical independent claims did not apply to the present case. No ***reformatio in pejus*** arose from the introduction of a claim directed to a membrane according to Claims 1 and 7 as granted in combination. Finally, a referral to the Enlarged Board of Appeal was unnecessary, in view of the case law and the absence of any conflicting decisions.

Amendments

Claim 1 was the combination of Claims 1 and 7 as granted. Claim 17 was the combination of Claims 18 and 19 as granted. The amendments in Claim 1 aimed at overcoming the grounds of opposition, in particular lack of novelty and inventive step. Those in Claim 17 aimed at overcoming the ground of opposition under Article 100(b) EPC. Hence, the 4th Auxiliary Request only contained combinations of claims as granted and was formally allowable.

Novelty and inventive step

The Board should exercise its discretion on whether or not to address the issues of novelty and inventive step. The proprietors were in favour of a decision, as the proceedings had gone on for many years and the case was in a state to be resolved.

XIV. The appellants opponents requested as main request that the decision under appeal be set aside and the patent be revoked, alternatively that there be referred to the Enlarged Board of Appeal the question of law to what extent are patent proprietors in appeal proceedings entitled to revert to a claim request which they abandoned before the Opposition Division, or that should the 4th Auxiliary Request filed at oral proceedings on 15 October 2009 be admitted into the proceedings that the matter be remitted to the first instance for further prosecution.

XV. The appellants proprietors requested that the decision under appeal be set aside and the patent be maintained on the basis of the Main Request, or the 1st, 2nd, or 3rd auxiliary requests filed 11 September 2009 or the 4th Auxiliary Request filed at oral proceedings on 15 October 2009, that no point of law be referred to the Enlarged Board of Appeal and that the Board decide the matter itself without remittal to the first instance.

Reasons for the Decision

1. The appeal is admissible.

Main Request

2. *Amendments*

Compared to Claim 1 as granted (Point II, ***supra***), concerning a "membrane material", Claim 1 according to the Main Request (Points IV and XI, ***supra***) is amended to define an "artificial kidney in which there is used a membrane material".

The term "artificial kidney" was not present in the claims as granted but is mentioned in some passages of the description as originally filed. The amendment thus consists in a feature taken from the description.

Since the amendment has been made during the opposition proceedings, the amended patent and the invention to which it relates shall comply with the requirements of the EPC (Article 101(3) EPC 2000) (see also Article 1,

Point 2, of the Decision of the Administrative Council of 28 June 2001 on the transitional provisions under Article 7 of the Act revising the EPC of 29 November 2000).

In particular, the requirements of Articles 84 and 123, paragraphs (2) and (3), EPC, as well as those of Rule 80 EPC, shall be fulfilled.

3. *Clarity*

3.1 It is not contested that the term "artificial kidney" is known to the skilled person as any article capable to mimic a renal function. The dispute concerns the reach of that definition, i.e. what subject-matter is clearly encompassed by that definition.

3.2 The questions which arise are whether or not Claim 1 is clear as regards the intended renal function of the defined artificial kidney, the properties that the membrane should possess to be able to mimic the intended renal function and the components of the artificial kidney other than the membrane, if any.

3.3 The application as filed does not mention any common general knowledge from which it might be gathered what falls under the term "artificial kidney".

3.4 As regards the intended renal function to mimic, the application as filed mentions that:
"*... various studies have been made in an attempt to develop dialysis techniques which function similarly to the human kidney in performing blood treatment for patients with chronic renal failure*" (Page 1, lines 19-

22, of the application as filed) (Paragraph [0002], first sentence, patent), and
"*When used for hemodialysis, hemofiltration, hemodialysis filtration, etc., therefore, a good performance is expected in improving the disease conditions of patients with renal failure. With its high water permeability, furthermore, the membrane can be applied to filtration for endotoxing removal for cleaning dialysate*" (last two sentences of the last paragraph on page 27 of the application as filed).

Hence, in the application as filed, no limitation whatsoever is imposed on the kind of dialysis or filtration to be carried out, let alone on the water permeability of the membrane (as invoked by the proprietors), which may well be high, as required for filtration. In particular, the removal of endotoxins from a dialysate *in vitro* only makes the subject of Claim 15 as filed.

3.5 The fact that the membrane has to mimic the intended renal function is mentioned in the description, as follows:

(a) "*Natural materials such as cellulose and synthetic polymer membrane materials such as polysulfone, polymethyimethacrylate (PMMA) and polyacrylonitrile have been widely used in semipermeable membranes for blood treatment*." (Page 1, lines 15-19, of the application as filed) (Paragraph [0002], first sentence, patent)).

(b) "*Of these membranes, much attention has recently been focused on polysulfone as it is sufficiently high in permeability to meet the latest improved dialysis techniques*." (Page 1, lines 22-25, of the

application as filed) (Paragraph [0002], second sentence, of the patent).

(c) *"As more than 20 years has passed since the advent of dialysis, many complications caused by long-term dialysis have been reported, especially recently, and attention is now focussed on proteins with molecular weights of 20,000 to 40,000 as causative agents of the carpal canal syndrome and other dialysis syndromes. None of the above patent publications, however, has disclosed a hollow yarn membrane that can play or imitate the role of the human kidney in positively removing such proteins as listed above"* (Page 3, line 28 - page 4, line 10 of the application as filed) (Paragraph [0004], last sentence, of the patent specification).

These passages relate to the description of what the membrane, in general or in particular, should do and make clear that the membrane is the essence of an artificial kidney, if not the artificial kidney, and that the required properties may change with time ("*especially recently*", "*attention is now focussed*", "*latest dialysis techniques*").

3.6 The term "artificial kidney" as such is found in two instances in the application as filed (all having corresponding counterparts in the specification of the patent in suit, indicated in a separate bracket):

(a) *"This washing step enables water soluble hydrophilic component present in the membrane to be washed out sufficiently to avoid heavy elution of the hydrophilic polymer which might otherwise occur during its use in an artificial kidney"* (sentence

bridging pages 10 and 11) (Paragraph [0019], page 4, lines 28-30).

(b) *"When only high molecular weight polymer chains are used, it will be impossible to achieve a low albumin permeability required for an artificial kidney, while maintaining a high water permeation performance"* (page 12, lines 17-20) (Paragraph [0021], page 4, lines 50-51).

Those two instances concern the washing step, in order to remove soluble material from the membrane, and the requirements of low albumin permeability and high water permeation. None of these conditions or requirements are defined in Claim 1. The albumin permeability is defined in Claims 11 to 13 as filed originally and in Claims 7 to 9 of the Main Request. The water permeability, not defined in any of the claims nor described in general ranges elsewhere in the description, is only mentioned specifically in the examples, so that the intended suitable range for any of the intended dialysis or filtration operations cannot be gathered. Hence, the instances mentioning "artificial kidney" concern the membrane as such, in particular its preparation and performance, which are not defined in Claim 1 of the Main request.

3.7 The components of an artificial kidney are not described either in the application as filed.

3.7.1 Example 1 (page 21, lines 8-10), referred to by the proprietors, illustrates a particular construction in which hollow yarn membranes were taken up at a speed of 40 m/min and packaged into a case so that its area became 1.6 cm^2, followed by potting to produce a module.

However, this specific module is not identified as an artificial kidney but as a module used to determine some of the properties of the membranes, such as albumin permeability and uremic toxin diffusion. Hence, it is not apparent whether the intended artificial kidney contains all the components of that module.

3.7.2 The fact that the application as filed (patent in suit) does not disclose what an artificial kidney is, i.e. how it is made up, results in it not being clear what parts (essential or ancillary), if any, are imported into Claim 1 by the introduction of "artificial kidney".

3.7.3 In particular, it is not clear whether or not the membrane as such fulfils the definition "artificial kidney". On this point, the opponents have changed their view after having for a while maintained that the membrane as such could be seen as an artificial kidney.

3.8 As regards the performance of a membrane for an artificial kidney, the application as filed (patent in suit) mentions that:

(a) *"The present invention relates to permselective membranes and to methods for their production. Specifically, it relates to permselective membranes which, when used for blood treatment, maintain a high hemofiltration rate and a low albumin permeability for a long period of time through control of the molecular weight distribution of the hydrophilic polymer in the membrane, and which are high in permselectivity to uremic toxins including medium-to-high molecular weight proteins, and also relates to methods for their production* (page 1, lines 4-13) (Paragraph [0001]).

(b) "*The crosslinking may work, for example, to connect chains of the hydrophobic polymer, i.e. the matrix, with those of the hydrophilic polymer to decrease the elution of the hydrophilic polymer, making it possible to produce modules that meet the artificial organs standards*." (Page 11, lines 16 to 20) (Paragraph [0020], first sentence).

It is apparent from the above that the application as filed (the patent in suit) mentions some requirements but does not disclose the set of requirements that have to be fulfilled by a membrane to be suitable for use in artificial kidneys. Moreover, several passages of the application as filed (or of the patent in suit) (*supra*) mention that the requirements to be fulfilled by the membrane can change with time as well, e.g. as a result of the discovery of any complications that may be caused by long-term dialysis.

Hence, it is not clear what requirement, if any, is imposed on the membrane, implicitly, by the definition "artificial kidney", beyond the features defined in Claim 1. If any requirement was actually imposed by the amendment artificial kidney, such as water permeability as alleged by the proprietors, the allowable range of values for that requirement, i.e. its extent, would not be clear either, because it is not defined in the application as filed, neither directly nor indirectly by reference to some standards.

3.9 In summary, the definition "artificial kidney" does not clearly set out all the features of the entities encompassed, let alone those of the membrane, so that further features beyond those specifically mentioned in

Claim 1 as granted cannot be identified in a direct and unambiguous way.

3.10 Consequently, all the claims of the Main Request containing the expression "artificial kidney", in particular Claim 1, are not clear (Article 84 EPC).

4. *Basis for the amendments and the amended claims*

4.1 On the other hand, even if it is assumed that the claims are clear, they are not based on the application as originally filed, for the following reasons.

4.2 The proprietors relied on a passage of the application as filed (sentence bridging pages 10 and 11) (Point 3.6(a), ***supra***) as a basis for the inclusion of the expression "artificial kidney" in the claims as granted.

4.3 However, that passage concerns the process of preparation of hollow fibres, in particular a step carried out under particular conditions to wash out excess hydrophilic components from the fibres, which might otherwise elute during the use of hollow fibre membranes in an artificial kidney.

4.4 Neither the character "hollow" of the membranes nor the particular hollow fibres obtained from said washing step, i.e. with reduced elution of the hydrophilic polymer component, are however defined in Claim 1.

4.5 The further instance in the application as filed in which "artificial kidney" is mentioned (Point 3.6(b), ***supra***) concern specific properties of hollow fibre

membranes such as albumin permeability and water permeability, none of which is defined in Claim 1 of the Main Request.

4.6 It follows from the above that the combination of the definition "artificial kidney" with the compositional definition of the membrane as made in Claim 1 as granted constitutes an intermediate generalization (i.e. to membranes beyond the hollow fibres, beyond those washed and treated as illustrated, as well as beyond those having the specific properties as defined in the application as filed when referring to "artificial kidney"), for which there is no direct and unambiguous disclosure in the application as filed.

4.7 Consequently, the claims containing the expression "artificial kidney", in particular Claim 1, do not meet the requirements of Article 123(2) EPC.

5. *Extension of the scope of protection*

5.1 The opponents have also objected that the amendment "artificial kidney" extends the protection conferred by the patent as granted (*supra*).

5.2 According to the proprietors' arguments (Point XIII, *supra*, Clarity), an artificial kidney contains not only a membrane suitable for haemodialysis but also more components such as tubing, fittings and controls, which fact is no longer disputed by the opponents.

5.3 Hence, the amendment "artificial kidney" implicitly imports in Claim 1 as granted not only more specific properties of the membrane, which actually would

restrict the scope of protection of Claim 1 as granted, but also operative components of an apparatus, which were not defined in any of the claims as granted and which (as the casing, the tubing, the valves, etc.) have no interrelationship with the membrane, i.e. are not suitable to impart any limitation to the membranes.

5.4 Since the product claims as granted defined a composition of matter (membrane material of Claims 1 to 9 and permselective material for use in dialysis of Claim 12), and since the amended product claims define an apparatus (an artificial kidney), there has been a shift of the definition of the invention from a physical entity to a more complex physical entity which was not encompassed by the terms of the claims as granted. That shift implies that further components of an apparatus are encompassed by the terms of the present claims. This extends the protection conferred by Claim 1 as granted to subject-matter which is foreign to that as granted (*aliud*), and so violates Article 123(3) EPC.

6. *Appropriateness of the amendments*

6.1 Questioned by the Board, the appellants proprietors have argued that the inclusion of "artificial kidney" in Claim 1 as granted serves the purpose of establishing novelty over the membrane of D2, which in their view was not suitable for artificial kidneys, because of too high a water permeability.

6.2 In view of the above conclusions, it may be left undecided whether or not the addition of the expression "artificial kidney", which does not clearly set out the

features of the membrane as claimed (Points 3., *supra*), and thus cannot impart any clear distinction over the membrane of D2, is appropriate for overcoming the intended ground of opposition.

1st and 2nd Auxiliary Requests

7. Claim 1 of each of 1st and 2nd Auxiliary Requests concerns an "**artificial kidney**" (emphasis by the Board), which for the reasons given for the Main Request contravenes the requirements of Articles 84 and 123, paragraphs (2) and (3) EPC. Hence, the claims of the 1st and 2nd Auxiliary Requests are not allowable either.

3rd Auxiliary request

8. Claim 1 of the 3rd Auxiliary Request (Point XI., *supra*) concerns a membrane material **for use in an artificial kidney** (emphasis by the Board).

8.1 For the reasons given in Points 2 (the claims as granted did not contain the expression artificial kidney) and 3 (in particular Point 3.8), *supra*, in relation to Claim 1 of the Main Request, the indication "for use in an artificial kidney" does not define what requirement (e.g. water or albumin permeability, clearance factor, elutable components, etc.), if any, is unambiguously imposed to the membrane material beyond the compositional requirement of Claim 1 as granted.

8.2 Consequently, Claim 1 is unclear (Article 84 EPC) and the 3rd Auxiliary Request, already for that reason, is not allowable.

4th Auxiliary request

9. The 4th Auxiliary Request submitted during the oral proceedings before the Board comprises 17 Claims, all of which, as detailed herein after, were present in the set of claims as granted.

Amendments

10. Claim 1 of the 4th Auxiliary Request results from the combination of Claims 1 and 7 as granted. Claim 17 results from the combination of Claims 18 and 19 as granted. Apart from any adaptation of their numbering or references, the other claims correspond identically to claims as granted: Claims 2-8, to Claims 2-6 and 8-9 as granted; Claims 9-11, to Claims 10-12 as granted; and, Claims 12-16, to Claims 13-17 as granted.

Procedural Questions - Admissibility of 4th Auxiliary Request

11. Both the opponents and the patent proprietors appealed the interlocutory decision of the Opposition Division.

11.1 The claims of the requests underlying the decision under appeal concerned artificial kidneys and a method of producing a polymeric membrane material.

11.2 The claims of the requests annexed to the statement setting out the grounds of appeal of the proprietors appellants respectively concerned: an artificial kidney (Main, and Subsidiary Requests 1 to 7), a use, in ***in vitro*** dialysis, of the membrane material (Subsidiary Requests 8 to 10) and a method of producing an

artificial kidney (Subsidiary Requests 11 and 12, as well as most of the previous requests as a further independent claim).

11.3 In response to a communication of the Board in preparation for oral proceedings, the proprietors appellants, with their letter dated 11 September 2009, submitted 18 fresh requests concerning respectively: an artificial kidney (Main, 1st, 2nd and 15th Auxiliary Requests); a membrane material for use in an artificial kidney (3rd to 5th and 16th Auxiliary Requests); a membrane material as defined in the claims as granted (6th Auxiliary Request); a more limited membrane material as in Claim 7 as granted (7th, 8th and 17th Auxiliary Requests); a method of producing an artificial kidney (9th and 12th Auxiliary Request); a method of producing a polymeric membrane comprising the features of Claims 1, 7 and 13 as granted (10th, 11th and 14th Auxiliary Requests); a method of producing a membrane for use in an artificial kidney (13th Auxiliary Request).

11.4 As regards the requests containing claims directed to a membrane material (3rd to 8th, 16th and 17th Auxiliary Requests), the opponents objected that the patent proprietors were not adversely affected by the decision under appeal, which did not deal with a membrane material, so that those requests were inadmissible.

11.5 The question of whether or not a party is adversely affected by a decision taken by an authority as defined in Article 106 EPC arises in connection with Article 107 EPC in order to establish who may appeal. In the present case, the proprietors were adversely

affected by the decision of the Opposition Division, which did not accede to e.g. their Main Request, so that the appeal of the patent proprietors was admissible, which fact is not contested.

11.6 The objection raised by the opponents indeed concerns the question of whether or not in opposition appeal proceedings broader claims (i.e. broader than those underlying the decision under appeal) may be reinstated (Case Law of the Boards of Appeal of the EPO, 5th edition 2006, VI.J.3.2.2(b)).

11.7 According to the case law (*supra*), where as in the present case the patent is maintained in amended form and the patent proprietors are themselves appellants, they may in appeal proceedings pursue claims which are broader than those held to be allowable by the Opposition Division.

11.8 However, the opponents have referred to T 528/93 (*supra*), mentioned in the case law (*supra*), in which it was decided that in appeal proceedings the patent proprietors may only pursue claims which were the subject of the decision at first instance, as they were not adversely affected with respect to claims requests that were not the subject of the decision under appeal, e.g. because the claims requests had been withdrawn before the Opposition Division. According to the opponents, that case was similar to the present one.

11.9 The case law (*supra*) also mentions decision T 168/99 of 12 December 2000, in which (Points 1. of the Reasons) it was decided that withdrawal of subject-matter (there, of the granted claims before the Opposition Division

had commented on them) did not necessarily mean that it had formally been abandoned. Hence, the reinstatement of the claims as granted as the Main Request was allowed, in particular because objections under Article 123, paragraphs 2 and 3, EPC had been raised against the requests containing amended claims.

11.10 It is apparent from the above that T 528/93 (*supra*) deals with claims being substantially identical, withdrawn before the Opposition Division and re-presented before the Board, whereas T 168/99 (*supra*) concerns a case in which there was no explicit abandonment of the claims as granted and issues under Article 123(2)(3) EPC were raised against the claims of the auxiliary requests.

11.11 Since in the present case the claims as granted had not been explicitly abandoned, Claim 1 of the 4th Auxiliary Request had never been presented before the Opposition Division and issues under Article 123(2)(3) were raised against the claims of the Main and 1st to 3rd Auxiliary Requests, the present case is similar to T 168/99 (*supra*) rather than to T 528/93 (*supra*).

11.12 Hence, there is no conflict with T 168/99 (*supra*) and the conflict between T 528/93 (*supra*) and T 168/99 (*supra*), if any, does not affect the present case.

11.13 In view of the case law (*supra*) and in the absence of any conflicting decision to the present case, a referral to the Enlarged Board of Appeal as invoked by the opponents is not necessary.

11.14 Therefore, the 4th Auxiliary Request is admissible.

Formal allowability of the Claims

12. The claims correspond identically to claims as granted, so that their basis is clear and their wording cannot be objected to. The opponents did not voice any formal objection against the amendments but required remittal of the case to the first instance. The Board has no formal objections against the 4th Auxiliary Request.

Remittal

13. The opponents have requested remittal if the 4th Auxiliary request were held to be admissible. The subject-matter of that request has never been dealt with before, so that substantive issues such as the alleged insufficiency of the disclosure, if maintained, novelty and inventive step have still to be argued and decided, whilst safeguarding the right to appeal of the parties. The Board, in the exercise of their discretion under Article 111(1) EPC, considers it appropriate to remit the case for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance for further prosecution on the basis of Claims 1 to 17 of the 4th Auxiliary Request filed at the oral proceedings on 15 October 2009.

The Registrar: The Chairman:

S. Fabiani S. Perryman