BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [ ] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 4 July 2012

Case Number: T 2026/09 - 3.3.07

Application Number: 98919641.5

Publication Number: 997182

IPC: B01D 71/68, B01D 69/08, A61M 1/16

Language of the proceedings: EN

Title of invention:
Polysulfone-base hollow-fiber hemocathartic membrane and processes for the production thereof

Applicants:
Asahi Kasei Medical Co., Ltd.

Headword:
-

Relevant legal provisions:
EPC Art. 84, 123(2)

Keyword:
"Clarity - parametrical definition - method of determination of the defined amount not clear - Main Request and Auxiliary Requests 1-4"
"Amendments -. fairly based on the application as originally filed (yes) - Auxiliary Request 5"
"Remittal (yes) - fresh case"

Decisions cited:
-

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 2026/09 - 3.3.07

D E C I S I O N
of the Technical Board of Appeal 3.3.07
of 4 July 2012

Appellants: (Applicants)
Asahi Kasei Medical Co., Ltd.
105, Kanda Jinbocho 1-chome
Chiyoda-ku
Tokyo (JP)

Representative:
von Kreisler Selting Werner
Deichmannhaus am Dom
Bahnhofsvorplatz 1
D-50667 Köln (DE)

Decision under appeal:
Decision of the Examining Division of the European Patent Office posted 14 April 2009 refusing European patent application No. 98919641.5 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: J. Riolo
Members: G. Santavicca
D. T. Keeling

Summary of Facts and Submissions

I. The appeal lies from a decision of the Examining Division, posted on 14 April 2009, refusing European patent application 98 919 641.5, filed on 18 May 1998 and published as EP 0 997 182 A1.

II. The application as filed contained 15 claims. Independent claims 1, 6 and 7 read as follows:

"1. A polysulfone type hollow fiber membrane for purifying blood in which membrane a selective separation layer exists on the internal surface side of the hollow fiber membrane and which membrane contains a polyvinyl pyrrolidone, wherein the polyvinyl pyrrolidone is contained in a proportion of 1 to 10% by weight, 5 to 50% of said polyvinyl pyrrolidone is soluble in water, and the concentration of the polyvinyl pyrrolidone on the internal surface of the hollow fiber membrane is in the range of 30% to 45%."

"6. A process for producing a polysulfone type hollow fiber membrane for purifying blood, which comprises subjecting a polymer solution comprising 15 to 20% by weight of a polysulfone type polymer in which solution the weight ratio of polyvinyl pyrrolidone to the polysulfone type polymer is from 0.25 to 0.5, to extrusion at a viscosity of 1,500 to 6,000 mPa.s, and to spinning at a draft ratio of 1.1 to 1.9 and at a linear extrusion velocity of not more than 90 m/min."

"7. A process for producing a polysulfone type hollow fiber membrane for purifying blood, which comprises spinning a hollow fiber membrane using a polymer

solution which comprises 15 to 20% by weight of a polysulfone type polymer in which solution the weight ratio of polyvinyl pyrrolidone to the polysulfone type polymer is from 0.25 to 0.5, and thereafter insolubilizing a portion of the polyvinyl pyrrolidone in the hollow fiber membrane by a physicochemical method."

III. The decision under appeal was based on amended Claims 1 to 15 submitted with letter of 2 June 2005 (sole claims request). Claim 1 was identical to Claim 1 as filed. Claim 6 read as follows (compared to Claim 6 as filed, additions are in bold and deletions in strike-through):

"6. A process for producing the polysulfone type hollow fiber membrane for purifying blood **according to anyone of claims 1 to 5,** which comprises **the following steps of, in this order,**

(a) obtaining ~~subjecting~~ a polymer solution comprising 15 to 20% by weight of a polysulfone type polymer in which solution the weight ratio of polyvinyl pyrrolidone to the polysulfone type polymer is from 0.25 to 0.5, ~~to extrusion~~

(b) **extruding said polymer solution** at a viscosity of 1,500 to 6,000 mPa.s and ~~to~~ spinning **the same** at a draft ratio of 1.1 to 1.9 and at a linear extrusion velocity of not more than 90 m/min, **and**

(c) insolubilizing a proportion of 95 to 50% of polyvinylpyrrolidone contained in the membrane by a physicochemical method and leaving a proportion of 5 to 95% of said polyvinylpyrrolidone to be water-soluble, in the presence of water containing a cross-linking inhibitor."

Claim 7 had been made dependent on Claim 6.

IV. In the decision, it was *inter alia* held that:

(a) There was no support for the feature "5 to 95%" in Item (c) of amended Claim 6 (Article 123(2) EPC), but this was a side issue and not a ground for refusal.

(b) The disclosure was insufficient (Article 83 EPC) as regards the way of measuring the amount of water-soluble PVP in the membrane, which was an essential and distinguishing feature of Claims 1 and 6, in so far the measurement conditions such as amounts of solvents and non-solvents as well as the temperature thereof were not disclosed.

(c) As to novelty, the applicants had not discharged their burden to prove that the broad parameter ranges in Claim 1 were not anticipated by the prior art products.

(d) Even if sufficiency of the disclosure and novelty were acknowledged, the claimed subject-matter would not involve an inventive step, as the alleged distinguishing feature (quantified presence of water-soluble PVP in the membrane) did not give rise to any unexpected result, as shown by e.g. comparing Example 4 and Comparative Example 2 of the application under examination.

(e) Having regard to all of those deficiencies, the application was to be refused.

V. With their statement setting out the grounds of appeal, the appellants submitted items of evidence as follows:

D6: Results of experimental tests, including Figures 1 to 4, performed on samples of hollow fibre membrane according to Example 1 of the application,

to respectively show how to test the solubility of the membrane in PVP, the amount of water for re-precipitating polysulfone (PSU), the temperature when re-precipitating the PSU as well as a (liquid chromatography (LC)) Chromatogramm.

D7: Comparative test results based on membranes according to D1 to D4, as summarised in a table on page 8 of the statement setting out the grounds of appeal.

VI. With letter of 30 May 2012, in response to the summons to oral proceedings, the appellants submitted a new set of Claims 1 to 10 and further items of evidence, namely:

D8: Experimental evidence, with Photographs i to iv, on the methodology of the determination of the amount of water-soluble PVP as described in the application;

D9: Picture of an evaluation of residual blood on membranes.

VII. In a communication in preparation for oral proceedings, dated 15 June 2012, the Board indicated the points that needed debate and decision. In particular, besides the compliance of the amendments to the claims of all requests with Article 123(2) EPC and a number of issues under Article 83 EPC, novelty and inventive step, the compliance of Claim 1 with Article 84 EPC was held to be crucial.

VIII. In response, the appellants, by letter of 29 June 2012, submitted 4 sets of amended claims, identified as Main Request and Auxiliary Requests 1 to 3, as well as still further items of evidence, as follows:

D9: Coloured version;

D10: Article on "Recrystallization (Chemistry)" retrieved from htpp://en.wikipedia.org/ on 27.06.2012;

D11: Ullmann's Encyclopedia of Industrial Chemistry, 1994, Vol.5, Analytical Methods, "Liquid Chromatography", pages 237 to 239;

D12: Ullmann's Encyclopedia of Industrial Chemistry, 1994, Vol.6, Analytical Methods, "X-ray Photoelectron spectroscopy (XPS)", pages 26 to 28;

D13: Article on "X-ray photoelectron spectroscopy" retrieved from htpp://en.wikipedia.org/ on 27.06.2012;

D14: Experimental results on D1 to D5, Pages 1-10.

IX. With letter faxed on 3 July 2012, the appellants submitted further sets of amended claims as their Main and Auxiliary Requests 1 to 4, thus replacing all of the claims requests then on file.

X. Oral proceedings took place on 4 July 2012. The appellants submitted fresh claims 1 to 4 as their Auxiliary Request 5. After the closure of the debate and deliberation by the Board the decision was announced orally.

XI. Claim 1 according to the Main Request filed on 3 July 2012 read as follows (compared to Claim 1 as filed (Point II., *supra*), additions are in bold and deletions in strike-through):

"1. A polysulfone type polymer hollow fiber membrane for purifying blood in which membrane a selective separation layer exists on the internal surface side of the hollow fiber membrane and which membrane contains ~~a~~

~~polyvinyl pyrrolidone, wherein the polyvinyl pyrrolidone is contained in a proprotion of~~ 1 to 10% by weight **of polyvinyl pyrrolidone (PVP) consisting of a portion insolubilized by crosslinking so that** 5 to 50% of ~~said~~ **the total amount of** polyvinyl pyrrolidone **contained in the hollow fiber membrane** is soluble in water, ~~and~~ **wherein** the concentration of the polyvinyl pyrrolidone on the internal surface of the hollow fiber membrane is in the range of 30% to 45%, **and wherein the thickness of the selective separation layer is 2 to 15 μm,**

- wherein the PVP concentration on the internal surface of the hollow fiber membrane is determined by an X-ray electron spectroscopy for chemical analysis (ESCA) by arranging samples on a double-sided tape, then cutting in the fiber axial direction by a cutter, and opening so that the internal side of the hollow fiber membrane becomes the surface, after which the opened samples are arranged and then subjected to measurement, wherein from the integrated intensities of C1s, O1s, N1s and S2p spectra the surface concentration (A) of nitrogen and the surface concentration (B) of sulfur are determined using the relative sensitivity factor appendant to apparatus, and the surface PVP concentration is calculated from the equation: surface PVP conc. = A x 100/(A x 111 + B x 442), and

- wherein the amount of the water-soluble PVP is the amount of the PVP in the membrane which is not insolubilized and is determined by completely dissolving the hollow fiber membrane in N-methyl-2-pyrrolidone, subsequently adding water to this polymer solution to precipitate the polysulfone type polymer, allowing it to stand and determining the amount of the

PVP in the resulting supernatant by liquid chromatography."

Claim 1 of each of Auxiliary Requests 1 to 4 filed on 3 July 2012 comprises the feature:

"wherein the amount of the water-soluble PVP is the amount of the PVP in the membrane which is not insolubilized and is determined by completely dissolving the hollow fiber membrane in N-methyl-2-pyrrolidone, subsequently adding water to this polymer solution to precipitate the polysulfone type polymer, allowing it to stand and determining the amount of the PVP in the resulting supernatant by liquid chromatography".

Claim 1 according to Auxiliary Request 5 filed during the oral proceedings held on 4 July 2012 is identical to Claim 6 as filed (Point II., *supra*).

XII. As far as they are relevant to the present decision, the arguments offered by the appellants can be summarised as follows:

Main Request

(a) As regards the amendments, Claim 1 included a clarification of the relative proportion between water-soluble and water-insoluble PVP, the additional features of Claim 5 as filed as well as the procedures for the determination of the PVP concentration on the internal surface of the hollow fibre membrane and for the determination of the water soluble PVP amount, all of which, albeit

shortened, were based on the application as filed. The other claims either dealt with the objections raised in the decision or corresponded to former claims, apart from adaptation of the dependencies. Thus, the amended claims were allowable.

(b) As to sufficiency of the disclosure, ample evidence had been provided that the determination of the amount of the water soluble PVP represented a procedure which was known to the skilled person. Such a procedure was based on basic chemistry tools such as multi-solvent recrystallization (disclosed in D10). In the present case three different polymers were present, two of which (polysulfone and crosslinked PVP) were soluble in N-methyl-pyrrolidone (NMP) or dimethyl formamide (DMF) but not in water, and the third (PVP not crosslinked) being soluble in water, even at ambient temperature. That procedure, as also shown in D8, thus consisted in:

(i) dissolving the hollow fibre in one solvent;
(ii) adding a nonsolvent for some of the polymers present, such as water;
(iii) completely precipitating some of the polymers while dissolving the not crosslinked PVP in water;
(iv) allowing the system to stand, e.g. overnight or over the weekend;
(v) filtrating the precipitate, and
(vi) analysing the supernatant for determining the amount of the polymer dissolved in water, by liquid chromatography.

All of these measures were conventional, albeit requiring reasonable conditions as shown in D6,

e.g. not a temperature of 100°C. The skilled person might find in handbooks and in the prior art appropriate solvents and non-solvents for every polymer. In particular, it was a known fact that polysulfone, PVP and crosslinked-PVP could completely be dissolved in N-Methyl-2-Pyrrolidone (NMP), and that polysulfone and crosslinked-PVP were insoluble in water. As regards liquid chromatography, such a method was well known for qualitative and quantitative determinations, and had been routinely used for 100 years, as disclosed in D11. This fact was also apparent from e.g. D1 (page 7, lines 16-22, was referred to), which albeit relating to a different methodology, confirmed that liquid chromatography was an usual technique. The skilled person could have chosen the appropriate liquid chromatography technique, might have tried to find the appropriate mobile phase and all operating conditions without undue burden. Hence, the claimed subject-matter had been sufficiently and clearly disclosed.

(c) As to clarity, merely on the basis of the items of information contained in the application, the determination of the amount of the water soluble amount of PVP defined in Claim 1 could have been carried out by trivial gravimetric methods, or even by the method disclosed in D1. So it was not credible that clarity might represent a problem for the definition of the water soluble amount of PVP. Neither D1 nor D4 (page 6, lines 21-32, was referred to) represented standards, on which the clarity of the definition of the methodology could be compared and decided. In this respect, D4 was

much less precise than D1. In any case, since only one amount had to be determined, despite the many possible methodologies, not much variation was involved in the results, i.e. all methodologies should give the same results. Summing up, the present application was written with the skilled person's eyes 14 years ago, whereby any missing item of information was to be supplemented by the common general knowledge of the skilled person. Hence, the claimed subject-matter had been defined in a sufficiently clear way.

Auxiliary Requests 1 to 4

(d) The above arguments applied ***mutatis mutandis*** to the claims of Auxiliary Requests 1 to 4, which were also more limited than those of the Main Request.

Auxiliary Request 5

(e) Apart from the necessary renumbering and adaptation of the references to the previous claims, Claim 1 was identical to Claim 6 as filed, Claim 2 was identical to Claim 13 as filed, Claim 3 was identical to Claim 14 as filed and Claim 4 was identical to claim 15 as filed. Thus, amended claims 1 to 4 of Auxiliary Request 5 were based on the application as filed (Article 123(2) EPC). These claims concerned the process for making the hollow fibre membrane and no longer contained the contested feature related to the amount of water soluble PVP and its determination.

XIII. The appellants (applicants) requested that the decision under appeal be set aside and that the case be remitted to the first instance with the order to grant a patent on the basis of the set of claims of the Main Request or one of Auxiliary Requests 1 to 4 submitted with letter of 3 July 2012 or to remit the case to the first instance for further prosecution on the basis of Auxiliary Request 5 submitted during the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

Admissibility of Main and Auxiliary Requests 1 to 4

2. The Main Request and Auxiliary Requests 1 to 4 were submitted on 3 July 2012, i.e. one day before the oral proceedings. Hence, the admissibility of these requests is at the discretion of the Board, as set out in Article 13 of the Rules of Procedure of the Boards of Appeal of the EPO (RPBA).

2.1 The submission was in reaction to the communication by the Board dated 15 June 2012, in which the claims of the previous requests had been objected to as ***inter alia*** lacking clarity (Article 84 EPC).

2.2 These claims requests do not raise any new issues which the Board could not reasonably be expected to deal with during the oral proceedings.

2.3 Therefore, the claims requests have been admitted.

Amendments

3. The amendments are fairly based on the application as filed (Article 123(2) EPC). Since the Main Request fails for lack of clarity (***infra***), the Board need not give further details on this issue.

Clarity

4. Claim 1 of the Main Request concerns a hollow fibre membrane, i.e. a physical entity, which is ***inter alia*** defined by the amount of water soluble polyvinyl pyrrolidone (PVP) which is still present in the membrane after insolubilisation by crosslinking (i.e. "5 to 50% of the total amount of PVP, which is 1 to 10% by weight), whereby this water soluble PVP amount is to be determined as specified in Claim 1, i.e.:
"wherein the amount of the water-soluble PVP is the amount of the PVP in the membrane which is not insolubilized and is determined by completely dissolving the hollow fiber membrane in N-methyl-2-pyrrolidone, subsequently adding water to this polymer solution to precipitate the polysulfone type polymer, allowing it to stand and determining the amount of the PVP in the resulting supernatant by liquid chromatography".

4.1 The amount of water soluble polyvinyl pyrrolidone is an essential and distinguishing feature of the claimed membrane over known membranes. This is not contested.

4.2 The definition of the amount of PVP per se is not objected to. Since the proportion of PVP in the

membrane is from 1 to 10% by weight based on the total weight of the membrane, and since 5 to 50% by weight of PVP are still soluble in water, it follows that the proportion of water soluble PVP in the membrane may be from 0.05 to 5% by weight.

4.3 The required determination of the still soluble amount of PVP, as defined in the claims and described in the application as filed, is however objected to. In the decision under appeal, it was found to lack sufficiency of disclosure under Article 83 EPC. In its communication of 15 June 2012, the Board however also raised objections under Article 84 EPC.

4.4 The objections under Article 84 EPC against the determination of the water soluble PVP as defined in Claim 1 were based on the fact that this definition lacks the operating conditions of the measuring method (i.e. relevant details such as what amount of N-methyl-2-pyrrolidone (NMP) should be used to dissolve what amount of fibre, how much water should be added to the polymer solution for complete precipitation of the polysulfone type polymer, at what temperature, for how long should this precipitate be allowed to stand, and finally what determination with what liquid chromatography is then to be carried out), none of which is ever defined or described in the application as filed. Hence, as regards the amount of water soluble PVP, Claim 1 gives no exact definition of the applicable measuring method. Neither does the description.

4.5 When parameters are used in the claims and no details of their measuring methods are supplied, the question

arises whether there is a problem with respect to Article 83 or 84 EPC. The answer to this question is important, for in opposition proceedings compliance with Article 84 EPC is examined only in cases where there has been an amendment, whereas compliance with Article 83 EPC can be examined without any restriction (Case Law of the Boards of Appeal of the EPO, 6th edition 2010, II.A.6.2).

4.6 This implies that in examination proceedings the question whether the matter for which protection is sought is clearly and sufficiently defined in accordance with Article 84 EPC arises even if the applicants were able to show that the skilled person using common general knowledge would be able to find a particular method for determining the defined amount, e.g. because varying results might be obtained when using different possible measuring methods. Hence, in examination proceedings, compliance with Article 84 EPC must be examined first.

4.7 The second sentence of Article 84 EPC stipulates that the claims must be clear (principle of clarity). The principle of clarity established by Article 84 EPC is an aspect of a broad general principle of law, i.e. legal certainty, namely the requirement that legal texts (such as claims) be clear and precise, which conveys the idea of predictability (scope and purpose of the text must be predictable).
Chemical products such as hollow fibre membranes may ***inter alia*** be defined by parametrical properties. As regards clarity, the questions arise as to whether the formulation of the parametrical definition can unambiguously define the sought-for subject-matter and

the claim enables the claimed subject-matter to be reliably distinguished from the prior art. Having regard to the specific situations in which these principles are to be applied, the requirement of clarity amounts to an "as clear as possible" definition (Münchner Gemeinschaftskommentar, 7th edition, May 1985, Article 84 EPC, Notes 76, 107 and 111).

4.8 The requirements of clarity to be fulfilled in case of parametrical definitions are well established (Case Law, *supra*, II.B.1.1.2). In particular: the parameter should be clearly and reliably determined by objective procedures which are usual in the art; where several methods exist, which fall under the definition as given, the following conditions must be met:

(a) the different methods yield essentially the same values; or,

(b) the skilled person would associate the range of the values of the parameter and its determination as defined in the claim with only one standard method of measurement.

This is especially applicable in examination proceedings, where the value of future legal certainty is paramount. Of course, the burden of proving that the skilled person would immediately associate with the method claimed the conditions to be applied even without any such indication in the claim lies on the applicants.

4.9 Hence, it must be decided whether, for the water soluble PVP present in the membrane after insolubilization by crosslinking, the generic definition of Claim 1 permits a clear and reliable determination by an objective procedure usual in the art. Since different methodologies appear to fall under

the generic terms (such as liquid chromatography) of the definition given in Claim 1, the question arises whether these different methodologies falling under the terms of Claim 1 would all give essentially the same results, or whether the skilled person would have associated any of them with the given definition.

Clear and reliable determination by objective procedures

4.9.1 Neither the claims nor the description of the present application define or illustrate with particulars how to determine, by the procedure as defined in the claims, the amount of water soluble PVP after insolubilization by crosslinking.

4.9.2 D1 and D4 (both concerning PVP-containing polysulfone hollow fibres for artificial kidneys) had been invoked by the appellants in support of the argument that the claimed determination, in particular the liquid chromatography, was usual in the technical field of the present application and could reliably be carried out by the skilled person.

4.9.3 D1 and D4 cannot be considered as standards for the definition and the description of the claimed measuring methods, as they are not handbooks. Nevertheless, they contain very specific descriptions of the evaluation methods used for the determination of their claimed parametrical features, which are similar to those used in the claims of the present application. Hence, they enable an insight into how similar methods are described in the art.

4.9.4 D1 (page 6, lines 40-49, and page 7, lines 16-22) gives the following illustrations for the liquid chromatographic determination and for the measurement of insolubilized material:

(4) Measurement of molecular weight distribution of polyvinyl pyrrolidone by gel permeation chromatography

A 100 mg portion of a hollow yarn after being subjected to required coagulation/rinsing processes was dissolved in 5 mg of methylene chloride before gamma-ray irradiation, and subjected to water extraction in the presence of a salt to obtain a solution. It was then subjected to centrifugal separation (20,000 rpm x 10 min) and the water layer was filtered through a filter with a pore diameter of 0.5 micrometers to obtain a sample liquid. Analysis of this liquid was carried out at a temperature of 23°C using two serially-connected Toso TSK-gel-GMPWx1 columns with a theoretical number of steps of 8,900 under the following conditions: 0.08M tris buffer (pH7.9) used as mobile phase, flow rate 1 ml/min, and sample loading 0.3 The molecular weight distribution was determined using five monodisperse polyethylene glycol products as reference material.

(7) Measurement of insolubilized material content

A 10 g portion of a hollow yarn irradiated with gamma-rays was prepared and dissolved in 100 ml of dimethylformamide at room temperature. The solution was subjected to centrifugal separation at 1,500 rpm for 10 minutes to separate insoluble material, and the supernatant liquid was discarded. This process was repeated three times. The solid material obtained was subjected to evaporation and exsiccation, and its weight was used to calculate the content of the insoluble material.

4.9.5 D4 (Page 6, lines 9-14 and 21-25) gives the following illustration for the insoluble component and for the cross-linked PVP content.

DMAc Insoluble Component

A mixture of 1g of the membrane dried at 120°C for 5 hours and 50ml of DMAc was thoroughly stirred fo 5 hours using a rotor, then filtered with a pre-weighed glass filter (2G-2), and the percentage (by weight) of th solid component obtained by drying at 130°C for 8 hours to the whole amount of the membrane was taken a the DMAc insoluble component.

Cross-linked PVP Content

The amount of PVP which became cross-linked was determined by measuring the amount of PVP dissolved out of the membrane by DMAc and subtracting this from the amount of PVP originally incorporated in the membrane.

4.9.6 It is apparent from the foregoing that D1 and D4 clearly specify almost all of the details, such as amount of fibre to be dissolved, amount of solvent, temperature, time, stirring conditions and kind of filters. As regards liquid chromatography, temperature, kind of column, number of steps, mobile phase, loading sample are given.

4.9.7 In contrast thereto, no detail whatsoever can be found in the present application.

4.9.8 So the determination as defined in Claim 1 cannot be carried out as clearly and reliably as illustrated by D1 and D4, which belong to the same technical field.

4.9.9 Indeed, the many missing items of information for carrying out the claimed method, still as apparent from the exhaustive illustrations of D1 and D4, rather lead to the conclusion that the generically claimed method does not represent an "as clear as possible" definition of an objective procedure in the art.

4.9.10 It thus remains to be decided whether further methods falling under Claim 1 could be applied to give essentially the same results, as maintained by the appellants on the basis of their evidence.

Further methods allegedly yielding essentially the same values

4.10 The information gathered from the evidence provided by the appellants (D6, D8 and D14) can be summarised as follows:

4.10.1 In D6, the experimental tests were carried out under the following conditions:

(a) (Figure 1) dissolution of hollow fibres membranes into NMP to respectively have 0.5/5.0/10/20 % of hollow fibre membrane concentration, at a temperature of 25°C, and re-precipitation of the polysulfone with water at an amount being 5-fold the amount of NMP, which conditions were said to be standard and applied throughout the test;

(b) (Figure 2) re-precipitation of polysulfone with an amount of water that was 0.25/0.5/0.75/1.0/5.0/10/40-fold the amount of NMP, at a concentration of hollow fibre membrane of 5% and a at temperature of 25°C, which conditions were defined as standard conditions applied throughout the test;

(c) (Figure 3) the temperature of re-precipitation was set at 25/50/70°C, whereas the concentration of hollow fibre membrane in NMP was set at 5.0% and the additive amount of water was 5-fold the amount of NMP, which defined as constant conditions applied throughout the test;

(d) Figure 4 shows an alleged example of chromatogramm of liquid chromatography. No detail of what has been actually made is however given.

4.10.2 The conditions used in the test of Figure 2 of D6 were also applied in the test summarised in D8 (Table on Page 4). Also in D8, no detail whatsoever of the liquid chromatography method applied is given.

4.10.3 The choices made in D6 and D8 represent very particular situations within the scope of Claim 1 of the Main Request, which lead to the following results:

(a) The determination of the amount of water soluble PVP gives the same results when:

(i) the hollow fibre concentration ranges from 0.5 to 10% (Figure 1);

(ii) the amount of water ranges from 1 to 40-fold the amount of NMP (Figure 2); and,

(iii) the temperature is set between 25 and 70°C.

(b) Instead, as stated in D6 and D8, some of the conditions tested do not work (well):

(i) at a hollow fibre concentration of 20%, too much time is required for dissolving and the viscosity of the solution becomes too high;

(ii) amounts of re-precipitation water of respectively 0.25, 0.5 and 0.75-fold the amount of NMP lead to incomplete precipitation of polysulfone as well as to jamming of liquid chromatography column, so this amount of water cannot be used.

(c) Hence, even within the few (purposively chosen by the appellants) conditions tested in D6 and D8, there are situations that, whilst falling under Claim 1, do not permit a reliable determination of the water soluble PVP content after insolubilization by crosslinking.

(d) Thus, as shown by D6 and D8, essentially the same results are obtained if the amount of hollow fibre and the amount of re-precipitation water are appropriately chosen, for which choice however no information, let alone for the conditions applied in D6 and D8, is given in the applications as filed.

4.10.4 In D14 (Point 2.2.2), ***inter alia*** a very particular liquid chromatography protocol is applied for the claimed determination, as follows:

"Water soluble PVP in membrane
0.1 g of each hollow fiber membrane sample was added and dissolved in 2 ml of NMP at room temperature. After NMP became transparent, 10 ml of water of 25°C was added thereto, and the mixture was slightly stirred to deposit polysulfone and other components. The supernatants were filtered off through a membrane filter (pore size: 0,45 μm), and the amount of PVP dissolved in the liquid component was then measured by liquid chromatography (LC).
The contents of the LC analysis were as follows:
Colum: Asahipak GF-710HQ (Showa Denko)

Temperature: 40°C
Mobile phase: 50mM NaC1 aq.soln.
Flow rate: 1 ml/mm
Detector: UV 220nm
Sample loading: 100 µl.
For the analysis, 6 types of aqueous PVP solutions differing in concentration were prepared in advance and analyzed by LC to determine the correlation of detection areas to PVP concentrations. This was used as a calibration curve."

The very particular protocol applied in D14 finds no counterpart in the application as filed, or in the available art invoked. Nor has any item of evidence been provided to show that if liquid chromatography is carried out with a different flow-rate, or sample loading, or temperature, or mobile phase, or if instead of the area of the peaks their height is used, essentially the same results would be reached.

4.10.5 It follows from the above analysis that it has not been convincingly proven that different methods falling under Claim 1 would provide essentially the same values when applied to the claimed determination.

Usualness in the art of the determination method as claimed

4.10.6 It follows from the foregoing that none of the cited documents mentions the method of measuring the water soluble amount of PVP as defined in Claim 1. D1 concerns PVP-containing polysulfone hollow fibres for artificial kidneys but discloses the application of a particular liquid chromatography, namely gel permeation chromatography, to the determination of the molecular weight distribution of PVP, which is not what is defined in present Claim 1. D10 is an internet extract concerning re-crystallization in general, not re-precipitation of polymer as applied in the present application. D11 generally concerns liquid

chromatography. Nevertheless, the question is not whether re-precipitation of polymer and liquid chromatography were known procedures before the effective filing date of the application, which facts are not in dispute. The question is whether the parameter and its determination as defined in Claim 1 were usual in the art at the effective date of filing of the application. On the basis of the evidence on file as analysed above, the claimed determination was not usual in the art. Hence, a further requirement for the clarity of a parametrical definition is not fulfilled.

Conclusion

5. It follows from the foregoing that the definition of the amount of the water soluble content of PVP after insolubilization by crosslinking given in Claim 1 is not as clear as it could be. The consequences thereof are as follows:

5.1 Since the skilled person does not know what measurement was intended by the applicants to be associated with the amount of still water soluble PVP after insolubilization by crosslinking, in order to delimit the scope of Claim 1, the determination thereof remains unclear, i.e. the skilled person has no information whatsoever about which methodology is to be used to assess whether he is working inside or outside the claimed scope, hence is left in a state of uncertainty.

5.2 Also, no meaningful comparison with the prior art can be made, which is particularly critical in the lower end portion of the claimed range (about 0.05% of water

soluble PVP), as a number of items of prior art concern substantial insolubilization of PVP.

5.3 It is apparent from the above that the lack of clarity due to the incomplete definition of the method for determining the water soluble PVP after insolubilization by crosslinking is prejudicial to the Main Request, which thus must be rejected.

Auxiliary Requests 1 to 4

6. Claim 1 of each of Auxiliary Requests 1 to 4 still contains the feature objected to concerning the determination of the water soluble PVP content, as in Claim 1 of the Main Request.

6.1 Hence, each Claim 1 of Auxiliary Requests 1 to 4 does not provide a "as clear as possible" definition of the matter for which protection is sought, inasmuch as the applicable measuring method remains doubtful, and legal certainty, which underlies the principle of clarity established in Article 84 EPC, cannot be established.

6.2 Therefore, none of Auxiliary Requests 1 to 4 fulfils the requirements of Article 84 EPC.

Auxiliary Request 5

Admissibility

7. Auxiliary Request 5 was submitted on 4 July 2012, i.e. during the oral proceedings. So the admissibility of this request is also at the discretion of the Board, as

set out in Article 13 of the Rules of Procedure of the Boards of Appeal of the EPO (RPBA).

7.1 The submission was in reaction to the debate during the oral proceedings, which was based on the objections as raised in the communication by the Board dated 15 June 2012, in particular clarity (Article 84 EPC).

7.2 This claims request is based on the claims as filed. It removes the objected to features, shifts the claimed subject-matter from product to process and overcomes the grounds of rejection as dealt with in the decision under appeal.

8. Therefore, Auxiliary Request 5 has been admitted.

Amendments

9. Auxiliary Request 5 is clearly allowable, as its Claims 1 to 4 are identical to Claims 6 and 13 to 15 as filed, apart from their numbering and references to previous claims, which have been amended accordingly. Hence, the requirements of Article 123(2) EPC are fulfilled.

Remittal

10. The grounds for refusal of the Main Request underlying the decision under appeal were lack of sufficiency of the disclosure, lack of novelty and lack of an inventive step arising from the alleged sole distinguishing feature of the then claimed subject-matter, namely the content of the water soluble PVP and

its determination, which was present in all independent claims.

10.1 Claims 1 to 4 of Auxiliary Request 5 submitted at the oral proceedings before the Board only concern the process of making the hollow fibre membrane as filed and no longer contain the definition of the water soluble PVP and its determination. Hence, the amended claims of Auxiliary Request 5 define a new combination of features, which was not dealt with in the decision under appeal and thus lies outside any review of the decision under appeal.

10.2 The appellants have requested a remittal to the first instance for further prosecution.

10.3 The shift to process claims does raise new issues, which the Board could not reasonably be expected to deal with, let alone during the oral proceedings, as they require further prosecution on subject-matter not dealt with by the decision under appeal.

10.4 The Board, in the exercise of its discretion under Article 111(1) EPC, considers it appropriate to remit the case to the Examining Division for further prosecution.

Further prosecution

11. The present decision only deals with compliance with Article 123(2) EPC (Auxiliary Request 5).

11.1 The decision whether or not the further requirements of the EPC are fulfilled by the claimed subject-matter of

Auxiliary Request 5 is left to the Examining Division, as the claims of Auxiliary Request 5 have not been dealt with in the decision under appeal.

11.2 It follows from the foregoing that the Board need not make any decision on the admissibility of the new items of evidence submitted during the appeal proceedings. Admissibility, if the issue arises, can better be dealt with by the Examining Division.

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 4 of the Auxiliary Request submitted at the oral proceedings on 4 July 2012.

The Registrar: The Chairman:

S. Fabiani J. Riolo