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Datasheet for the decision of 18 November 2016

Case Number: T 2348/13 - 3.3.06

Application Number: 96304795.6

Publication Number: 0750936

IPC: B01D67/00, B01D71/68, B01D69/08, A61M1/16

Language of the proceedings: EN

Title of invention:
Permselective membranes and methods for their production

Patent Proprietor:
TORAY INDUSTRIES, INC.

Opponent:
Fresenius Medical Care AG

Headword:
Permselective membrane / TORAY

Relevant legal provisions:
EPC Art. 52(1), 54, 56, 84, 100(b), 123(2)

Keyword:
Amendments - allowable (yes)
Sufficiency of disclosure - (yes)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:
T 1188/00, T 0867/05

Catchword:

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Case Number: T 2348/13 - 3.3.06

D E C I S I O N
of Technical Board of Appeal 3.3.06
of 18 November 2016

Appellant: (Patent Proprietor)	TORAY INDUSTRIES, INC. 2-1, Nihonbashi Muromachi 2-chome, Chuo-ku Tokyo 103-8666 (JP)
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Respondent: (Opponent)	Fresenius Medical Care AG Frankfurter Strasse 6-8 66606 St. Wendel (DE)
Representative:	Ricker, Mathias Wallinger Ricker Schlotter Tostmann Patent- und Rechtsanwälte Partnerschaft mbB Zweibrückenstrasse 5-7 80331 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 9 September 2013 revoking European patent No. 0750936 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman B. Czech
Members: G. Santavicca
S. Fernández de Córdoba

Summary of Facts and Submissions

I. The appeal lies from the decision of the Opposition Division, posted on 9 September 2013, to revoke European patent n° 0 750 936.

II. The patent as granted is concerned with membrane materials, their preparation and their use in permselective filtration, more particularly in dialysis.

III. The patent had been opposed on the grounds of lack of novelty, lack of inventive step and insufficiency of the disclosure.

The prior art relied upon included documents
D2: JP 63 097 205 A (English Translation) and
D9: EP 0 168 783 A1.

IV. The Opposition Division also admitted into the proceedings the following items of evidence (*inter alia*) filed after the expiry of the opposition period:

D26: WO 92/18224 A1 and
D27: Test Report by Dr. Stefan Athenstädt, dated 18 October 2012.

V. In the decision under appeal, the Opposition Division found that none of the claim requests then on file met all the requirements of the EPC. In particular, the Opposition Division found that having regard to Claims 1 to 17 according to the pending Main Request (claims already found to be "formally" allowable by the Board entrusted with the case in decision T 867/05 of 15 October 2009)
- the claimed subject-matter was novel over D2 and D26,

and
- the claimed invention was sufficiently disclosed,
- but the subject-matter of Claim 1 did not involve an inventive step in the light of D9 taken as the closest prior art, considering also documents D2 and D27.
Since the claimed subject-matters according to the then pending Auxiliary Requests 1 to 6 were also found to be objectionable on the ground of lack of inventive step, the patent was revoked.

VI. Independent Claims 1, 9, 11, 12 and 17 of the Main Request rejected by the Opposition Division read 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, and wherein the membrane material has an overall mass transfer coefficient (K_0), for a Stokes' radius of at least 30 Å, as determined by a diffusion test using dextran, of at least 0.0025 cm/mm* [sic] *or more and a permeability to albumin of 4% or less.*"

"9. *Use of a membrane material according to any*

preceding claim in an in vitro permselective filtration process."

"*11. A permselective material, for use in dialysis, comprising a membrane according to any one of claims 1-8.*"

"*12. A method of producing a polymeric membrane as claimed in any one of claims 1 to 8, 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.*"

Dependent claims 1 to 8, 10 and 13 to 17 are directed to more specific membrane materials, uses and methods.

More particularly, dependent method Claim 17 reads as follows:

"*17. A method according to any one of Claims 12 to 16, which includes the subsequent step of subjecting the membrane to an insolubilization step, wherein the insolubilization is carried out by subjecting the membrane material to cross linking by γ-ray irradiation.*"

VII. In its statement setting out the grounds of appeal dated 20 January 2014, the Appellant (Patent Proprietor) defended the patent in the versions according to said Main and Auxiliary Requests dealt with in the decision under appeal. It contested the finding of the Opposition Division regarding lack of inventive step. It also submitted that D26 and D27 should not have been admitted into the proceedings in view of their late filing and lack of relevance, and that they should thus be disregarded by the Board.

In support of its argumentation regarding inventive step, it submitted further items of evidence (D31 to D38), with

D31: Experimental Report re D9 and Section 2 of D27, January 2014; and

D32: Technical Report re Section 3 of D27, January 2014.

VIII. In its reply of 13 May 2014, the Respondent (Opponent) requested the non-admittance of any of documents D31 to D38, in particular of Experimental Reports D31 and D32, in view of their late filing and lack of relevance. It also announced that further experiments regarding the disclosure of D9 were being carried out.

IX. With its letter dated 2 August 2014, the Respondent maintained the request not to admit D31 to D38 and filed further evidence, *inter alia*

D39: Second Experimental Report by Dr. Athenstädt,

to be considered in case Experimental Reports D31 and D32 were admitted into the proceedings.

The Respondent maintained its objections regarding lack of novelty over D2 (conditional) and D26, lack of inventive step in the light of D9 or D26, and insufficiency of the disclosure.

X. The parties were summoned to oral proceedings.

XI. With letter dated 5 October 2016, the Appellant filed further items of evidence D40 to D44 to corroborate its position regarding the disclosure of D9 and unexpected effects allegedly achieved by the invention, with

D40: US 3,691,068 (cited in D9);
D41: Technical Report 1, September 2016, 9 pages; and,
D44: Technical Report 2, September 2016, pages 1-3.

XII. In a further letter dated 11 October 2016, the Respondent *inter alia* requested the non-admittance of new documents D40 to D44 and of the arguments based thereon, which amounted to an amendment of the Appellant's case, into the proceedings. Otherwise, the oral proceedings should be postponed, in order to permit a proper evaluation of these submissions and to provide counter-evidence, if expedient.

XIII. In a communication faxed on 4 November 2016, issued in preparation for the oral proceedings, the Board expressed its provisional opinion on some salient issues of the case, *inter alia,*
- that it saw no reasons to overrule the decision on the admissibility of documents D26 and D27;
- that D40, acknowledged in D9, appeared to be admissible;
- that D42 and D43 were post-published and did not appear to concern common general knowledge;

- that the admission of further technical reports D31, D41, and D44 depended on whether D27 was found to be a correct and relevant reproduction of D9, so that these reports might be found to be inadmissible;
- that the arguments brought forward by the Appellant in its letter of 5 October 2016, objected to by the Respondent as an amendment to the Appellant's case, did not appear to be fresh lines of arguments;
- that only if D41 and D43 were admitted, the request to postpone the oral proceedings would be considered;
- that none of the five objections raised by the Respondent against sufficiency were convincing, and that the Board had no reason to deviate from the decision under appeal in this respect;
- that the claimed subject-matter appeared to be novel over D2 and D26;
- that D9 was the closest prior art document;
- that the technical problem effectively solved appeared to consist in the provision of a further membrane material having properties as akin as possible to those of human kidneys;
- that the claimed subject-matter did not appear to be obvious over D9 alone, nor over its combination with any of D2 or D26, let alone over D26 alone.

XIV. With letter dated 16 November 2015, the Respondent submitted the following further prior art document

D45: DE 2 236 226 A.

allegedly showing the operating conditions used in D9, and took once more position as regards its sufficiency and inventive step objections.

XV. By letter of 16 November 2016, the Appellant took stance on the latest objections by the Respondent and

submitted additional information on the process conditions used to reproduce a membrane according to Claim 1 in D44.
It indicated that D9 was acknowledged in the application as filed as JP-B-05 054 373. Moreover, it submitted that the comparison with the reproduction of D27 made in D44 was not a fresh line of arguments and that the filing of D44 aimed to further develop an argumentation already presented in the statement of grounds.

XVI. Oral proceedings were held on 18 November 2016.

The parties had no further comments concerning the admissibility of D26 and D27 into the proceedings in view of the preliminary opinion expressed by the Board in its communication.

They were heard regarding the Main Request, more particularly regarding
- novelty over D26 and
- inventive step in the light of D9, D26 and D2.

As regards novelty and inventive step in the light of D2, as well as its insufficiency objection, the Respondent relied on its written submissions.

XVII. Final Requests

The Appellant (Patent Proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims according to the Main Request or, in the alternative, the claims according to one of the First to Sixth Auxiliary Requests, all requests filed with the statement setting

out the grounds of appeal.

The Respondent (Opponent) requested that the appeal be dismissed.

XVIII. The arguments of the Appellant of relevance for the present decision can be summarised as follows:

Amendments to parties' cases

If D31 and D32 were not admitted into the proceedings, D39 should not be admitted either.
The comparison with D27 made in D44 was not a fresh line of arguments but a further elaboration of a line of defence already included in the statement of grounds of appeal. Thus, D44 should be admitted.

Novelty

Example 4 of D26 did not directly and unambiguously disclose all of the features of Claim 1 at issue, let alone the molecular weight distribution and the overall mass transfer coefficient (K_0).
As the PVP having a K-value of 85-88 used in Example 4 of D26 was most similar to the PVP (BASF K-90) used in Comparative Example 2 of the patent in suit, the PVP of D26 could not have the claimed distribution of molecular weights. Also, even if it were acceptable to take some items of information from the general, preferred disclosure of D26, the choices made in D27 did not supplement but modified Example 4 of D26.
In fact, D27 differed from Example 4 of D26 in several instances, such as the different polymers used, the shorter distance between spinneret and quenching bath as well as the higher concentration of isopropanol in the diluent solution. Thus, D27 could not show that

Example 4 of D26 was novelty destroying.

D2 was not novelty-destroying, as it did not disclose the use of a PVP displaying the claimed distribution of molecular weights. Moreover, D2 neither disclosed the use of the invoked PVP K-60, nor the relative amounts of PVP and PS as claimed, let alone the compliance of the described membrane materials with the performance parameters defined in Claim 1 at issue.

Inventive step

D9, acknowledged in the application as filed as JP-B-05 054 373, in particular its Example 1, disclosed the closest prior art for assessing inventive step.
The technical problem stated in the patent in suit was effectively solved by the claimed invention, as shown by the examples of the patent.
The claimed subject-matter was not obvious in view of D9, taken alone or in combination with D2 or D26.

D9 did not disclose a molecular weight distribution determined by gel permeation chromatography as called for in Claim 1 at issue. Moreover, D9 did not directly and unambiguously disclose that the amount of PVP remaining in the membrane was at least 3 wt.%.
Although D9 contained some general statements on the amount of PVP, the amount thereof remaining in the membrane of its Example 1 was not disclosed. Moreover, D9 (page 15, lines 18-25) taught a content of 90-99 wt.%, preferred 95-98 wt.%, of a first polymer (PS). The content of the second polymer (PVP) in the membrane of Example 1 might thus be 1-10, preferably, 2-5 wt.%. As the patent in suit required a minimum of at least 3 wt.%, part of the disclosure of D9 (from 1 to less than 3 wt.%) was outside the claimed range.

Thus, Example 1 of D9, did not directly and unambiguously disclose an amount of PVP in the membrane within the range of Claim 1 at issue. Nor had it been proven that an amount of 3 to 15 wt.% of PVP would inevitably remain in the membrane of Example 1 of D9.

Also the overall mass transfer coefficient Ko was not disclosed by D9. Whilst claimed coefficient Ko was a measure of diffusion, the sieving coefficient disclosed by D9, and mentioned in its Figure 8, was obtained by forcing a fluid through a membrane, thus was a measure of convection and diffusion. D9 was not concerned with diffusion, as the patent in suit, but had to do with a sieving coefficient, which was not directly comparable with K_0, as same sieving coefficient did not mean nor imply same overall mass transfer K_0. Indeed, D9 merely taught that smaller proteins diffuse better whilst bigger proteins permeated better under ultrafiltration conditions. The argument that it was plausible that the K_0 requirement was fulfilled also by the membrane of Example 1 of D9, which was able to mimic the human kidney, was not sufficient to establish an unambiguous disclosure. In this respect attention was drawn to D41 and to Figure 8 of D9, the latter giving no answer to the question of what went through the membrane.

As regards the extrapolation of K_0 carried out by the opponent, in order to show that the membrane of Example 1 of D9 had the claimed coefficient, it was not contested that the relationship might in some cases be linear, but it was disputed that it was universally so. Figure 2 of the patent in suit, relied upon by the opponent as basis for the extrapolation, concerned a relative comparison within the disclosure of the patent in suit, *inter alia* encompassing comparative examples, such as Comparative Example 3, using a PVP K-30,

whereby the K_0 was not linear with the Stoke's radius. The invoked linear relationship for determining the K_0 value could not be used for a comparison between the patent in suit and D9, as it amounted to a selection of values specifically chosen for the calculation.
Even if it were considered that K_0 was related to the clearance, Figure 2 of D9 showed that it would depend on the blood flux Qb, as the values at Qb 200 were different from the values at Qb 300, and no linearity either was apparent. Thus, the extrapolation did not prove any unambiguous disclosure.

Summing up, D9 did not directly and unambiguously disclose a membrane with an amount of PVP of at least 3 wt.%, having the claimed molecular weight distribution determined by gel permeation chromatography, and an overall mass transfer coefficient K_0 as defined.

Nor was this combination of features obvious over the cited prior art, for the following reasons:

In general, D9 did not rely on the extension of the diffusion, which was very tiny if any. Instead, as the patent in suit showed, the claimed membrane permitted a genuine meaningful separation effect without transmembrane pressure when the overall mass transfer coefficient Ko had the minimum required value of at least 25 micrometers per minute. This value meant that, for a membrane of 50 micrometer thickness, a protein with a Stoke's radius of 30 Å transited across it in two minutes. Hence, a valuable contribution to dialysis was achieved. Instead, D9 taught that a change of the clearance to increase removal of β2MG was achievable by changing the filtration rate.

The Respondent had pointed to specific items of

disclosure in D9 without explaining why the skilled person would have been motivated to pick them up in combination. In particular, why he would have replaced the PVP K-30 used in Example 1 of D9 with a PVP K-60 to K-90, or a mixture of PVP K30 and K-90, nor why he would have wanted to have at least 3 wt.% of a PVP K-60 in the membrane. As D9 did not hint at using a PVP mixture, it was not clear how the skilled person would have arrived at the molecular weight distribution.

The claimed subject-matter was not obvious either over any of the combinations of D9 with D26 or with D2.

Even if the skilled person had considered D26, in particular its Example 4, it would have found that the use of 2.8 wt.% of PVP with a K-value of 87 was most preferred. Hence, if he had replaced the 9 wt.% PVP of Example 1 of D9 with the PVP K-87 of D26, he would have come to a content of at most only 2.8 wt.%.

D2 disclosed a membrane having a too high water permeability for use in membrane dialysis, so that the skilled person would not have obviously considered its combination with D9.

Sufficiency of the disclosure

The Respondent had not proven the alleged insufficiency. The patent taught how to measure the parameters claimed. The skilled person would have no problem modifying the conditions used according to the examples, but remaining within the ambit of the claims.

XIX. The arguments of the Respondent of relevance for the present decision can be summarised as follows:

Amendments to Appellant's case

None of Experimental Reports D31 and D32 should be admitted, in view of their late filing and lack of relevance. The second Experimental Report by Dr Athenstädt (D39) was to be considered if Experimental Reports D31 and D32 were admitted into the proceedings.

D40 to D44, and the new arguments based thereon, constituting an amended Proprietor's case, should not be admitted into the proceedings. D40, referred to in D9, should not be admitted into the proceedings due to its lack of relevance. D45, instead, also acknowledged in D9, was more relevant and could be considered. Whilst Technical Report D27 was a faithful reproduction of Example 1 of D9, D44 lacked any information about material and process conditions used, and should not be admitted. The argument that an improved "β2MG" (β_2-microglobulin) clearance" was a surprising technical effect of the claimed membrane, based on D44, invoked in the Appellant's submission of 5 October 2016, was a fresh line of defence raised at a late stage of the proceedings, which should thus not be admitted into the proceedings. If the amended case based on these new items of evidence were admitted, the oral proceedings should be postponed in order to permit evaluation of these submissions and, possibly, the production of counter evidence.

Lack of novelty

Example 4 of D26 was novelty-destroying for the subject-matter of Claim 1 (Main Request). It disclosed

the preparation of a membrane with a PVP having a K-value of 85-88, which as such fulfilled the molecular weight distribution requirement defined in Claim 1 at issue. This was apparent from the reworking carried out in D27, which took into account also the preferred general disclosure of D26, in particular that a PVP with a K-value of 85 to 88, more particular 87, was preferred. It was also clear from the examples of the patent in suit that whilst the use of PVP with a K-value of 90 or 30 lay outside the invention, a PVP with a K-value of less than 90, such as 87, complied with Claim 1. All of these polymers contained macromolecules of PVP of molecular weights higher and lower than 100,000, as defined in Claim 1 at issue. Hence, the membrane prepared according to D27, based on Example 4 and on the preferred information of D26, had all of the features of Claim 1 at issue.
Consequently, Example 4 of D26 was novelty destroying.

The claimed material lacked novelty over the membrane material disclosed in D2 (pages 10 and 11), disclosing the use of PVPs as also used in the patent (e.g. PVP-K60) (thus inevitably displaying the claimed molecular weight distribution). Under the condition that the performance parameters defined in Claim 1 were the direct consequence of the fulfilment of the molecular weight distribution of Claim 1 at issue, such a membrane according to D2 would inevitably display the performance properties required by the claims at issue.

Lack of inventive step

If it was found that the skilled person in the relevant technical field was able to supplement the teaching of the patent in suit based on common general knowledge and, hence, to carry out the claimed invention, such

knowledge had also to taken into account when assessing the information content of D9, D27 and D39, as well as inventive step.

On that basis, the subject-matter of (at least) claims 1 and 12 at issue did not involve an inventive step in the light of D9 in combination with D26, and/or in the light of D2 alone, if the performance parameters of Claim 1 were the direct result of the choice of the molecular weight distribution.

D9, in particular its Example 1, was the closest prior art to be considered in assessing inventive step. It disclosed a membrane which was a barrier for molecules having molecular weights greater than 30.000 to 40.000 Da (Dalton), and it mentioned a significant clearance for myoglobulin (MW 17500 Da). As D9 addressed the problem of removal of medium size molecules, it inherently implied the prevention of the problems occurring in long term dialysis.

The technical problem solved in the light of D9 was as stated in paragraph [0004] of the patent in suit and consisted in providing a further membrane material having properties as akin as possible to those of the human kidneys.

It was not contested that this problem stated in the patent in suit was solved as shown by the examples of the patent in suit.
However, the subject-matter as defined in Claims 1 and 12 was obvious over D9 taken alone, as this document directly or implicitly disclosed all of the claimed features, or in combination with either D26 or D2.
The lack of an inventive step was even more apparent if the performance parameter values specified in Claim 1

were considered to be a direct result of the molecular weight distribution specified in Claim 1 at issue.

As regards the question of which features of Claim 1 were disclosed by D9, the following should be noted:

Example 1 of D9 disclosed the preparation of a membrane material comprising polysulfone (PS) as hydrophobic polymer and polyvinyl pyrrolidone (PVP) as hydrophilic polymer.

According to D9 (page 18, line 24), that membrane ensured a very low permeability for albumin as defined in Claim 1 at issue.

As to the requirement of a minimum content of 3 wt.% of PVP in the membrane, D9 taught (page 11, lines 23-25) that its membrane preferably contained 5 to 8 wt.% of PVP. Hence, the disclosure of D9 was in significant overlap with the range defined in Claim 1 at issue, so that this feature was disclosed by D9. Questioned by the Board on why Point 5 of D27 did not mention any determination of the content of PVP in the tested membrane, the Opponent's answer was that it did not know, *inter alia* as Example 1 of D9 did not disclose all the spinning parameters.

D9/Example 1 did not explicitly disclose the molecular weight distribution and the overall mass transfer coefficient K_0 defined in Claim 1. However, according to the patent in suit, the performance characteristics such as the overall mass transfer coefficient (K_0) value were the direct result of the molecular weight distribution, i.e. of the presence of the respective molecular weight fractions in the defined proportions.

Even if the overall mass transfer coefficient were no the direct result of the choice of the molecular weight distribution, it was plausible that the membrane of D9 displayed an overall mass transfer coefficient as defined in Claim 1. In fact, D9 disclosed (page 18, lines 24-26, and page 25, last paragraph, in connection with Figure 8) that the filtration behaviour of its membranes was most similar to that of the human kidney, i.e. that proteins of molecular weights within the range 20 000 to 40 000 Da were significantly removed. Figure 8 and page 18, line 23, disclosed a significant clearance for myoglobulin (MW 17500 Da). As shown in Figure 8, and as disclosed on page 5, lines 8-10, the membranes of D9 were a barrier for molecules having molecular weights greater than 45.000 Da. Coefficient K_0 defined in Claim 1 at issue represented nothing more than the properties mentioned in D9.

The alleged difference between the diffusion of the patent in suit and the convection of D9 was not credible. In the measurements carried out in the patent in suit with a particular blood flux, a certain amount of ultrafiltration, as in D9, was always present.

That the K_0 value of the membrane of Example 1 of D9 was as defined in Claim 1 at issue was also apparent from D27 (Points 2 and 3), according to which the membrane of Example 1 of D9 had a measured K_0 of 0.0027 cm/min, which was in line with the value of 0.0028 cm/min calculated on the basis of the values of the clearances given in the patent in suit. The linearity of the extrapolation made in D27 (Point 3) was fairly based on the curves of Figure 2 of the patent in suit, which clearly showed a tendential linearity of the K_0 value from 0 to 30 Stoke's radii. The argument of the Patent Proprietor that the clearance in Figure 2 of D9

depended on the flux Qb was a speculation, in so far Figure 8 of D9 clearly showed the capabilities removal of the membrane of D9. Figure 2 of D9 merely showed that higher fluxes led to better partition between bigger and smaller molecules. Proteins such as myoglobulin were anyhow removed.

Therefore, the overall mass transfer coefficient K_0 was implicitly disclosed in D9.

As regards the obviousness of the claimed subject-matter, the following was noted.

D9 (page 11, line 25) explicitly disclosed that a PVP content of 5-6 wt.% in the membrane was preferred, e.g. in order to improve wettability. The skilled person starting from D9 was motivated at keeping a minimum content of PVP in the membrane, preferably at a level of at least 5 wt.%.

D9 (page 9, lines 14-19) taught the importance of PVP for forming the pores but required (page 11) a control of the viscosity of the two-polymer blend. D9 hinted at using PVPs with a molecular weight ranging from 10,000 to 450,000, such as those designated K-15 to K-90. Among them, the skilled person would not have wanted to use those which would be washed out easily, such as the K-15. Hence, he would have wanted to use PVPs such as K-60 to K-90, provided that the viscosity requirements of D9 (page 11) were complied with. As shown in the patent in suit, these PVPs (mixtures) had the claimed distribution of molecular weights. The choice of these PVPs made within the list of polymers of D9 was not a novel purposive selection but a hinted option.

As regards the overall mass transfer coefficient K_0, it

was a functional, unusual parameter with respect to D9. In fact, D9 taught how to manufacture a membrane able to mimic the human kidney, to remove medium molecular weight proteins such as myoglobulin but not bigger proteins such as albumin. Over Example 3 of D9, showing all classical conditions for dialysis, the patent in suit provided no distinction whatsoever. It had not been proven that diffusion (as argued by the Patent Proprietor) was so relevant for the dialysis. Moreover, the patent in suit (paragraphs [0006] and [0021]) taught that the performance characteristics such as the overall mass transfer coefficient (K_0) value were the direct result of the molecular weight distribution requirement of Claim 1. Thus, the K_0 value was either at least implicitly disclosed in D9 or obvious.

D9 could also be supplemented by any of D26 or D2.

D26 taught the use of PVPs having K-values of 85-88, hence of lower molecular weights than PVP K-90 used in the patent in suit. Thus, their molecular weight distribution would be within the range defined in Claim 1 at issue. It was also apparent from D26 (page 7, lines 18-22) that, in order to control the viscosity, the skilled person had two possibilities: reduce the amount of PVPs with K-values of 80 or more; or use a mixture of two PVPs, a K-90 and K-30. Of course, the skilled person would have wanted to use the mixture of PVPs. These mixture had the claimed molecular weight distribution according to the patent in suit.
D2 contained an explicit disclosure of a PVP K-60 in a short list of possible embodiments. The choice of this PVP within the short list was obvious, despite the fact that the examples of D2 used PVP K-90.

Summing up, the skilled person starting from Example 1

of D9, using 9 wt.% of PVP with molecular weight 40 000, following the indications of D9 (all PVPs K-15 to K-90 are suitable) would (routinely) try the use of 9 wt.% of PVP K-60. Even if he considered D26, Examples 4 or 8, which use 2.8 wt.% of a PVP K-87, or D2, he would try to use a PVP K-60 in an amount of at least 5 wt.% as suggested by D9. As shown by D27, the membrane of D9 had anyhow a K_0 value as claimed.

Therefore, the skilled person following the hints given in D9, at least those concerning the PVPs, having a distribution of molecular weights as claimed, possibly combined with D26 or D2, would obviously have arrived at the subject-matter of Claim 1 at issue, which consequently was not inventive.

Insufficiency of the disclosure

The claimed subject-matter was insufficiently disclosed, for the following reasons:

(1) Claim 1 did not define when the determination of the molecular weight distribution feature was to be done, nor did it disclose how to determine the claimed molecular weight distribution of PVPs in a cross-linked membrane, encompassed by Claim 1 at issue;

(2) if the properties defined in Claim 1 were not the direct result of the molecular weight distribution of the PVP, the invention could not be reproduced, as no necessary operating conditions therefor had been disclosed;

(3) it was not plausible that, as shown by Example 1, a membrane has a K_0 value of 0.0025 cm/min for a Stokes' radius of 45 Angstroms and, at the same time, an

albumin permeability of only 1.4%, as albumin has a size of 33-35 Angstroms;

(4) the patent in suit did not disclose all relevant manufacturing parameters for obtaining a membrane as claimed, and they were not common general knowledge;

(5) in view of the objections raised by the Patent Proprietor regarding the length of the dialysis apparatus used by the Respondent in its experiments, the determination of the parameter K_0 was not sufficiently disclosed in the patent in suit.

Reasons for the Decision

Main Request

1. Formal allowability of the amended claims

1.1 The amended claims at issue were found to be formally allowable in the earlier decision T 0867/05 of 15 October 2009 (Reasons 12, concerning these claims then pending as Auxiliary Request 4).

1.2 The Board observes that the measuring unit "cm/**mm**" of the coefficient K_0 defined in the claims is manifestly mistyped, since a mass transfer coefficient cannot have as its unit a ratio of lengths. In accordance with paragraph [0007] of the patent, the correct unit is understood to be "*cm/**min***".

2. Admissibility issues - late filed evidence and amendments to the parties' cases

2.1 Admittance of D26 and D27 by the Opposition Division

In its communication issued in preparation for the oral proceedings, the Board indicated that it saw no reason that could possibly justify overruling the Opposition Division's discretionary decision to admit and consider D26 and D27.

This view was thereafter no longer challenged by the Appellant.

2.2 No need arose to decide on the admittance of further items of evidence cited in these appeal proceedings

Although, as announced in its communication, the Board was inclined to accept that D40, acknowledged and referred to in D9 (closest prior art), be admitted into the proceedings, considering that it might have shed light on the process conditions used in D9, thus on the relevance of D27, D40 did not play any role during the oral proceedings. This was also the case with D45. Hence, no decision needed to be taken as regards the admittance of these documents.

2.3 As already indicated in the Board's communication, post-published articles D42 and D43 do not illustrate common general knowledge and do not appear to concern polysulfone membranes nor haemodialysis. Moreover, these documents did not play any role during the oral proceedings either, so that no decision needed to be taken as regards the admittance of these documents.

2.4 The further technical reports D31, D32, D39, D41 and D44 are supposed to further corroborate earlier submissions regarding the (implicit) disclosures of D9 and D26, the relevance of D27 or the technical effect to be achieved according to the invention. A necessity

to deal with the question of their admissibility into the proceedings and their relevance would only arise in case the Board were to consider that D27 is a correct and relevant reproduction of example 1 of D9. Since, as apparent from the following (Point 4.4, *infra*), D27 is not considered to describe a relevant reproduction of Example 1 of D9, the admissibility of these documents need not be dealt with either.

In particular, the Board need not decide whether late-filed experimental reports D31, D32, D39, D41 and D44 are sufficiently complete, whether Reports D31 and D39 do refer to the conditions disclosed in D9 and whether D44 (see Point (5)) discloses what membrane according to Claim 1 has actually been prepared, and how.

In fact, none of the experimental reports D31, D32, D39, D41 and D44 was invoked in the course of the debate that took place at the oral proceedings before the Board. The further cited documents such as D33 to D38 have not been invoked either during the oral proceedings.

Hence, there is not need to take a decision regarding the admissibility of all these items of evidence.

2.5 Admittance of allegedly new lines of arguments presented by the Patent Proprietor in its letter of 5 October 2016

2.5.1 As to the first line (i.e. D27/Example 1 was based on inappropriate selection of coagulation bath temperature, thus was not a faithful reproduction), already in its statement setting out the grounds of appeal (page 8, first sentence, and fourth full paragraph with table), the Patent Proprietor argued

that an experiment such as D27, involving the choice of several process conditions not disclosed in D9, but affecting the properties of the membrane (including K_0), *inter alia* the coagulation bath temperature of 84°C, could not be considered a reproduction of Example 1 of D9.

Hence, the first allegedly new line of argument merely appears to further develop earlier arguments regarding one of the parameters of D27, allegedly not disclosed in D9.

2.5.2 Also the second allegedly new line of argument, i.e. that the PVP molecular weight distribution of the membrane according to the patent in suit caused a surprising technical effect, namely an improved beta microglobulin clearance, appears to have already been presented in the statement setting out the grounds of appeal (page 15, third full paragraph to last paragraph; page 26, first paragraph). At most, the comparison with D27 made in D43 might be considered to be new, and raises the question whether it is a further elaboration of an existing line of defence, or a fresh line of defence.

However, the Board holds that these arguments do not amount to a fresh line of defence and therefore considers further on the consequences of this view under points 8, *infra* (Technical problem).

2.6 In respect of the request of the Respondent in its letter of 11 October 2016 (Point I.2) to postpone oral proceedings, if the new lines were admitted, as, as also foreshadowed in the Board's communication, none of D41 and D43 were considered during the oral proceedings, no need of postponing or continuing the

oral proceedings at a later date for the debate on inventive step over D9 arose.

Main Request - Sufficiency of the disclosure

3. The Respondent based its insufficiency objections on several lines of arguments (see pages 20 and 21, supra), dealt with in sequence below.

3.1 First, Claim 1 did not define how/when compliance with the molecular weight distribution feature was to be ascertained, in particular in the case of a cross-linked membrane.

3.1.1 Indeed, the claims as granted do not specify at what point in time the determination of the molecular weight distribution of the PVP in the membrane is to be done, i.e. before or after crosslinking.

3.1.2 Sufficiency of the disclosure is, however, to be assessed taking into account the whole content of the patent and the relevant common general knowledge.

3.1.3 It clearly emanates at least from paragraphs [0020] (sentence bridging pages 4 and 5), [0030], [0032] and [0034] of the patent in suit, that the claimed molecular weight distribution of the PVP has to be met (measured by gel permeation chromatography) prior to insolubilization (i.e. crosslinking). In fact, the method disclosed in paragraph [0030] is **expressly** to be carried out "*before gamma irradiation*", as also shown in Example 1. The determination of the remaining PVP by elemental analysis is, however, carried out on an irradiated sample (paragraph [0032], Example 1).

3.1.4 Thus, the skilled person would know how and when to

determine the claimed parameters, as described. No evidence to the contrary is on file.

3.2 Second, if the physical properties (such as permeability and diffusion) of the membrane as defined in Claim 1 were not the direct result of the molecular weight distribution of the PVP component, then the invention could, allegedly, not be reproduced.

3.2.1 It emanates from the patent in suit that the properties defined in Claim 1 do not depend solely on (i.e are not the direct result of) the molecular weight distribution of the PVP. For instance, paragraph [0021], first full sentence on page 5, states that
"To achieve such characteristics as described above, furthermore, the content of the hydrophilic polymer in the membrane should be 3-15 wt.%".

3.3 According to the third objection, it was not plausible that, as shown by Example 1, a membrane has a K_0 value of 0.0025 cm/min for a Stokes' radius of 45 Angstroms and, at the same time, an albumin permeability of only 1.4%, as albumin has a size of 33-35 Angstroms. However, the Respondent has not provided any evidence showing that the albumin permeability value of Example 1 was higher, e.g. than the upper limit of the claimed range (4%).

Hence, for the Board, it has not been established that Example 1 concerns a non-working embodiment, which might not be reproduced, nor that Claim 1 encompasses non-working embodiments.

3.4 Fourth, the patent in suit does not sufficiently disclose all relevant manufacturing details/parameters permitting to obtain a membrane as claimed, and this

could not be complemented on the basis of common general knowledge.

3.4.1 In opposition (appeal) proceedings the burden of proof of insufficiency generally lies with the Opponent. This burden has not been discharged, as no convincing evidence is on file. Indeed, the experimental reports submitted by the Opponent, e.g. D27 (and D39, if it were admissible), appear to show that the skilled person has no problem to produce a membrane material according to Claim 1.

3.4.2 The Board also notes that the patent in suit
- acknowledges prior art relating to polysulfone/PVP membranes, and, more importantly,
- contains examples showing how to carry out the invention.

It has not been shown that the skilled person was not able to follow and/or vary these examples in order to obtain further membranes with the claimed physical characteristics while remaining within the ambit of Claim 1 at issue.

3.5 Fifth, in so far the Appellant/Patent Proprietor contends that an unusually long (44cm) dialysis apparatus has been used by the Respondent in its experiments D27 for determining K_0, the determination of the parameter K_0 is not sufficiently disclosed in this respect in the patent in suit.

3.5.1 This objection appears to be only a reaction to the criticism by the patent proprietor on the unusual length of the dialysis apparatus used in D27. The objection does not take into account the whole

disclosure and the common general knowledge, and is not backed up by verifiable evidence.

3.6 Summing up, the Respondent has not convincingly shown that, at the priority date, the skilled person, considering the whole disclosure of the patent in suit and taking into account the relevant common general knowledge was not able to carry out the claimed invention in order to achieve a membrane material with the required performance characteristics.

3.7 The Board thus sees no reasons for overturning the finding of the Opposition Division and concludes that the invention as claimed is not objectionable under Article 100(b) EPC.

Novelty

3.8 Novelty over document D2

3.9 The Appellant's novelty objection is based on the assumption that the mention, in D2, of using mixtures of commercially available PVPS, including PVP-K60, amounted to a disclosure of a PVP molecular weight distribution in accordance with the claims at issue.

3.10 The Board, however, does not consider this assumption to be correct for the following reasons:

3.10.1 Although D2 mentions a PVP K60 (page 10, lines 15-16), PVP K90 is used according to all of the examples of D2, since high molecular weight PVP is considered to be advantageous (D2: page 10, lines 22-25).

3.10.2 It has not been shown that the use of said PVP K-90 would inevitably result in a molecular weight

distribution, determined by gel permeation chromatography, as defined in the claims at issue.

3.10.3 The general statements in D2 (page 10, lines 13-17, and page 11, lines 10-12) regarding the possible use of mxitures of the listed commercially available PVPs, do not find any specific concretization therein.

3.10.4 Neither has it been shown that a membrane prepared from the PVPs used according to the examples of D2 would have an albumin permeability of less than 4%.

3.11 Consequently, none of the embodiments of the membrane materials illustrated in the examples of D2 has been shown to directly and unambiguously, at least implicitly, have this molecular weight distribution, let alone any allegedly consequential performance properties.

4. Novelty over document D26

4.1 Example 4 of D26 does not disclose literally a membrane material with all the features of Claim 1, i.e. a PVP molecular weight distribution, a minimum residual PVP content, an overall mass transfer coefficient K_0 and an albumin permeability as required by the claim.

4.2 D27 describes *inter alia* an attempt to reproduce Example 4 of D26 experimentally. However, the specific experimental conditions applied according to this reproduction are neither mentioned in Example 4, nor in some other passage of D26 that would be applicable to said example.

The Board notes, for instance, the following differences between what is described in example 4 of

D26 and the experimental work described in D27:

- The composition of the diluent solution supplied to the spinneret is different: Example 4 of D26 discloses 70.5 wt-% isopropanol and 29.5 wt-% reverse osmosis distilled water, whilst according to D27 (point 4) a diluent solution comprising **75** wt-% of isopropanol was used.

- Example 4 of D26 does not mention a crimping step occurring according to D27.

- The temperatures of the spinneret head are not the same, namely 23°C to 24°C in Example 4 of D26, 20°C according to D27 (Point 4).

- The distance between the spinneret and the quenching bath differs also: 1.5 m in Example 4 of D26, 1 m according to D27, Point 4).

4.3 However, as even acknowledged in D26 itself (e.g. page 9, lines 12 to 14; page 11, lines 8 to 21) the composition of the diluent solution affects the properties of the fibres prepared, e.g. their porosity, clearance and flux.

4.4 For the Board, the membrane obtained according to the reproduction attempt described in D27 is thus not the inevitable result of the process described in more general terms in Example 4 of D26. It is, instead, the result of a process which is
a) modified in the knowledge of the present invention and
b) a more specific process than the one described in Example 4 of D26, which is not directly and unambiguously disclosed in D26.

4.5 Hence the Board holds that Example 4 of D26 does not even implicitly disclose in an unambiguous manner a membrane material falling within the ambit of Claim 1 at issue.

5. Therefore, in the Board's judgement, the subject-matters of Claim 1, of independent Claims 9, 11 and 12 directed to applications of the membrane material of Claim 1 at issue or its preparation, and of the dependent claims, are novel over the prior art invoked by the Respondent (Article 52(1) and 54 EPC).

Inventive step

6. The Invention

6.1 The invention relates to semipermeable membrane materials, their use in permselective filtration and to methods for their production (see independent Claims 1, 9, 11 and 12 quoted under Point VII, *supra*).

6.2 In the description of the patent (paragraphs [0001] and [0005]), the following is respectively stated as regards the permselective membrane of the invention:

"The present invention 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

"*we found a permselective membrane, in accordance with the invention, which allowas a dialysis technique to be carried out during which the membrane minimizes the permeability to albumin, a useful protein, while at the same time maintaining a high water permeability, and efficiently removing medium-to-high molecular weight uremia-causing proteins*".

7. The closest prior art

7.1 At the oral proceedings, it was common ground between the parties that D9 discloses the closest prior art. Considering the similarities between the subject-matter of the patent in suit and of D9 in terms of the technical issues addressed and the membranes disclosed, the Board has no reasons to take a different stance.

7.2 Indeed, D9 addresses (page 5, lines 6 to 10; page 6, lines 17 to 22) the problem of providing membranes for hemodialysis having excellent wettability, low content of extractable substances, very good hydraulic permeability combined with good mechanical properties, as well as excellent biocompatibility and separation properties similar to those of a human kidney.

7.3 In Example 1 a preparation process is described according to which a hollow fibre membrane is manufactured from a polymer solution including 15 wt.% Polysulfone and 9 wt.% PVP, which has a dense layer of 1 micrometers thickness and contains an unspecified (page 20, last paragraph) remaining amount of PVP which makes the membrane obtained water-wettable.
In Example 3 of D9 (pages 23 to 25) the properties of the membrane so obtained are summarised and commented. More particularly, Example 3 expressly mentions the clearance increase for *inter alia* β-MG (beta-

microglobuline) in hemodialysis, which according to the Respondent was a protein of medium molecular weight size.

8. The technical problem

The Appellant argued that in the light of D9 the technical problem consisted in providing membrane materials improved in term of their performance in separating undesirable proteins causing dialysis syndromes, minimizing the permeability to albumin and achieving effective mass transfer performance.

9. The solution

The patent is suit proposes, as a solution to the problem posed, the "*membrane material*" according (amended) Claim 1 at issue which is characterised in particular in that (emphasis added by the Board):
it comprises "*a polysulfone as a hydrophobic polymer and a polyvinyl pyrrolidone as a hydrophilic polymer, wherein* ***the PVP is present in the membrane in an amount of 3-15% by weight of the total weight of PS and PVP***",
wherein
"*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_0), for a Stokes' radius of at least 30 Å, as determined by a diffusion test using dextran, at***

least 0.0025 cm/mm *[sic] or more and a* ***permeability to albumin of 4% or less***".

10. Technical problem formulated by the Appellant not successfully solved

10.1 As regards the benefits allegedly achieved in comparison to prior art membranes, including those according to D9 (reference is made in the patent to a corresponding application JP B 05 054 373), the patent merely contains the following statement (paragraph[0004]):

"*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***", i.e. proteins with molecular weights of 20 000 to 40 000 which are causative agents of carpal canal syndrome and other dialysis syndromes (paragraph [0004] of the patent).

10.2 According to established case law of the Boards of Appeal (see e.g. decision T 1188/00 of 30 April 2003, Reasons 4.5, 4.8-4.10) an improvement over the prior art invoked for the first time in the opposition appeal proceedings cannot be relied upon in arguing that a more ambitious technical problem is solved, unless it is plausibly demonstrated that the alleged improved effect can be achieved across the whole scope of the claim. The burden of proof lies with the Patent Proprietor in this respect.

10.3 Evidence potentially relevant in this respect

10.3.1 Example 1 of D9 does not disclose the amount (rest) of PVP remaining in the membrane. According to the alleged

reproduction of this example (D27, Table in Point 5), any remaining PVP is not quantified either, whilst it is apparent that the membrane contained 68.5% PVP with a MW of less than 100000, i.e. more than the required 50%.

Example 3 of D9 refers to an increase in clearance but neither disclose the absolute clearance for β-MG, nor any of the other performance characteristics required by Claim 1 at issue.

None of the comparative examples of the patent in suit, refers to a membrane as disclosed in D9.

Technical Report 2 (D44) contains a comparison between the β-MG clearances of
- the membrane described in D27 and supposed to be a reproduction of a membrane according to D9,
and
- a membrane according to Claim 1, which is, however, not precisely described in D44 (Point (5)), which merely mentions that the membrane is produced according to Claim 1 and has all parameters of Claim 1, and in this respect is contested by the Respondent.

10.3.2 Thus, for the Board it has not been convincingly shown (not even by D44, if it were held admissible) that an improvement in terms of relevant membrane performance parameters is effectively achieved in comparison to a prior art membrane according to D9, let alone across the whole breadth of Claim 1.

10.4 Reformulated technical problem

Consequently, the technical problem solved in the light of D9 must be re-formulated in a less ambitious way

according to paragraph [0004] of the patent. It can be seen in providing a further membrane material having properties similar to those of a human kidney.

11. The success of the solution

11.1 As apparent from the experimental data reported in the the examples of the patent in suit the membranes according to the invention meet these requirements. This is not disputed.

11.2 Hence, the Board accepts that said less ambitious technical problem (point 10.4, *supra*) is effectively solved by the claimed membrane material.

12. Obviousness

12.1 It therefore remains to be decided whether the claimed subject-matter was obvious to the person skilled in the art having regard to the state of the art.

12.2 D9 taken alone

12.2.1 D9 (Example 1 and general description) does not hint at using a PVP with a molecular weight distribution as claimed, let alone present in the finished membrane at a minimum residual level of 3 wt.%. Although D9 (Example 3) mentions the increase in clearance removal of β-MG, this document does not specifically address the problem of long-term dialysis complications due to the insufficient removal of proteins with molecular weight of 20 000 to 40 000. Example 3 of D9 merely suggests to increase the filtration flux in order to improve also the clearance of β-MG, i.e. to act on operating conditions of the dialysis rather than on the

properties of the membrane.

12.2.2 Therefore, the person skilled in the art would not, in the light of the contents of D9 taken alone, and without hindsight, consider modifying/implementing the membrane preparation method described in Example 1 of D9 such that a membrane material falling under the ambit of Claim 1 at issue is obtained.

12.3 Combination of D9 and D2

12.3.1 D2 concerns a method of treating a polysulfone resin translucent film in order to obtain a translucent film having extremely high water permeability. In particular, D2 concerns membranes prepared from mixtures of PVP as hydrophilic polymer and together with polysulfone. D2 generally teaches that commercially available PVP having molecular weights of 360000, 160000, 40000, and 10000 can be used, and that polymers having different molecular weights may be used in mixtures thereof (page 11, lines 10-12).

However, in D2 (page 10, lines 22-25) a preference is expressed for high molecular weight PVPs. The examples of D2 only disclose the use of a PVP with a K-value of 90 as a component of the film forming composition. Moreover, it was not shown that this PVP necessarily has a molecular weight distribution according to Claim 1 at issue.

12.3.2 Hence, the Board holds that D2 cannot induce the skilled person to modify/implement the preparation process disclosed in D9/Example 1 in such a way that it would result in a membrane material displaying all the features of Claim 1 at issue.

12.4 Combination of D9 with D26

12.4.1 D26 (see also Points 4, *supra* as regards the disclosure of this document) addresses the problem of improving production rates of the membranes over the prior art (page 3, Summary of the invention), which is a quite different objective than that of the patent in suit. D26 does not touch upon the selective clearance removal of β-MG at all, but is essentially focusing on the rejection of albumin (page 17, lines 1-3).

12.4.2 The membrane material of D26 contains PS and PVP, but D26 (page 7, line 14) teaches to preferably use a PVP with a K value of between 85-90, since a PVP with a K value less than 80 may result in the unwanted formation of voids in the wall (lines 18-20). D26 teaches away from using any PVP with a K-value of less than 80.

Thus, in D26 a preference is expressed for PVPs of high average molecular weight (this is apparent from a calculation from the formula on page 7, line 5, of the patent in suit, for a K-value of 90), and not for the use of PVP with a K-value of 60, or a combination of PVPs of K-values of 90 and 30 as exemplified in the patent in suit.

It was not convincingly pointed out based on which particular consideration the person skilled in the art would have considered moving from the PVP K-30 of Example 1 of D9 to the PVP K-85/K-88 of D26, which provides more viscous dopes not preferred by D9.

12.4.3 As regards the amount of PVP amount remaining in the membrane, D26 merely teaches that the "some" polymer remaining in the membrane increases its water wettability (page 7, lines 24 to 26).

The examples of D26 indicate the amount of PVP in the dope, but not the amount of PVP ultimately remaining in the prepared membrane. Example 4 of D26 uses a dope comprising 2.8 wt.% of a PVP K85-88. This is also the case in Examples 5 and 6.

According to Examples 7 and 10 a dope comprising 4.8 wt.% PVP of K-value 85 to 88 is used. However, this results in a dope having a viscosity of 3500 cP at 25°C, which is higher than the viscosity value preferred according to D9 (i.e. 3000 cP at 20°C, see page 11 of D9).

Hence, a PVP amount of at least 3 wt.% remaining in the membrane material is not a requisite of D26 either.

12.4.4 The objection of lack of an inventive step based on D26/Example 4 taken alone, raised in the letter dated 2 August 2014, was no longer pursued during the oral proceedings. Based on the considerations developed above (Points 12.4.1-12.4.3), it is immediately apparent that such attack would not succeed.

12.5 Based on the above considerations, the Board concludes that the subject-matter of Claim 1 at issue involves an inventive step as regards the state of the art invoked by the Respondent (Articles 52(1) and 56 EPC). Consequently, the subject-matters of the further claims likewise involve an inventive step.

Conclusion

13. The claims according to the Respondent's Main request are not objectionable on the grounds invoked by the Appellant.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of:
   - the claims according to the Main Request filed with the statement setting out the grounds of appeal;
   - Figures 1 and 2 of the patent specification;
   - a description to be adapted where appropriate.

The Registrar: The Chairman:

D. Magliano B. Czech

Decision electronically authenticated