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Datasheet for the decision of 20 July 2022

Case Number: T 1941/19 - 3.2.02

Application Number: 03781225.2

Publication Number: 1572330

IPC: A61M1/16

Language of the proceedings: EN

Title of invention:
PERM SELECTIVE ASYMMETRIC HOLLOW FIBRE MEMBRANE FOR THE SEPARATION OF TOXIC MEDIATORS FROM BLOOD

Patent Proprietor:
Gambro Lundia AB

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 54, 56
RPBA Art. 12(4)

Keyword:
Novelty - (yes)
Inventive step - (yes)
Late-filed evidence - admitted (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 1941/19 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 20 July 2022

Appellant: (Opponent)	Fresenius Medical Care Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg (DE)
Representative:	Stolmár & Partner Patentanwälte PartG mbB Blumenstraße 17 80331 München (DE)
Respondent: (Patent Proprietor)	Gambro Lundia AB Box 10101 220 10 Lund (SE)
Representative:	Hornung, Veronika Margot c/o Gambro Dialysatoren GmbH Holger-Crafoord-Strasse 26 72379 Hechingen (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 26 June 2019 rejecting the opposition filed against European patent No. 1572330 pursuant to Article 101(2) EPC**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	D. Ceccarelli
	Y. Podbielski

Summary of Facts and Submissions

I. The opponent appealed against the Opposition Division's decision to reject the opposition against the European patent.

The patent was opposed on the grounds of insufficient disclosure, extension of subject-matter, lack of novelty and lack of inventive step.

In the previous decision T 1608/13 concerning the same opposition, the competent board ruled that the ground for opposition of insufficient disclosure did not prejudice the maintenance of the patent as granted.

II. Since both parties had requested oral proceedings as an auxiliary measure, the Board summoned them to oral proceedings and sent its preliminary opinion in a communication dated 12 May 2022.

In this communication, the Board explained its view that the appellant's objections of lack of novelty and inventive step over document

E1: WO 96/37282 A1

were not convincing, and explained its intention not to admit into the appeal proceedings document

B1: EP 0 305 787 A1.

Consequently, the Board pointed out that the appeal would likely be dismissed.

III. By letter dated 8 June 2022 the appellant submitted that it would not be represented at the oral proceedings.

The oral proceedings were then cancelled by the Board.

IV. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the appeal be dismissed.

V. Claim 1 of the patent as granted reads as follows:

"A permselective asymmetric hollow fibre membrane for the separation of toxic mediators from blood, comprised of at least one hydrophobic polymer and at least one hydrophilic polymer, wherein a separation layer is present in the innermost layer of the hollow fiber characterized in that said membrane allows passage of molecules having a molecular weight of up to 45 000 Daltons with a sieving coefficient of 0.1-1.0 in presence of whole blood,
and has a nominal cut-off of 200,000 Daltons, with a sieving coefficient of 0.1, in water."

Claims 2 to 13 are dependent claims.

VI. The appellant's arguments, insofar as they are relevant to the decision, are summarised as follows.

Interpretation of features

The feature of the membrane allowing "passage of molecules having a molecular weight of up to 45 000 Daltons with a sieving coefficient of 0.1-1.0 in presence of whole blood" defined in claim 1 was

fulfilled by any membrane having the specified sieving coefficient with respect to at least one molecule with a molecular weight in the range of 0 to 45 000 Dalton. This assertion was based on case law relating to claim definitions of ranges.

The patent did not disclose any particular function or technical effect of the feature of the membrane having "a nominal cut-off of 200,000 Daltons, with a sieving coefficient of 0.1, in water" defined in claim 1. The only apparent function of this feature was that the membrane did not let any very large molecules pass, which was inherent for every membrane. Hence, this feature had no technical meaning and was not to be considered for novelty and inventive step, according to established case law.

Admissibility of B1

B1 had been introduced into the appeal proceedings because it was *prima facie* highly relevant, in particular for the feature of the membrane allowing "passage of molecules having a molecular weight of up to 45 000 Daltons with a sieving coefficient of 0.1-1.0 in presence of whole blood", derivable from Figure 3. B1 had been cited and considered in the examination of the application, which led to the grant of the patent.

Novelty in view of E1

E1 disclosed a membrane with a sieving coefficient between 0.1 and 1 for Cytochrom C, which had a molecular weight in the claimed range between 0 and 45 000, in presence of whole blood. It also disclosed a sieving coefficient of 0.1 for molecules with a molecular weight of 500 Dalton and 60 000 Dalton

(page 6, penultimate paragraph, and claim 5). The range of 500 to 60 000 Dalton overlapped with the claimed range of 0 to 45 000 Dalton.

It followed that E1 was novelty-destroying for the subject-matter of claim 1.

Inventive step in view of E1

The objective technical problem solved by the invention as claimed in the patent as granted could only be that of providing an alternative membrane which could remove as many toxic mediators as possible from the blood and keep as many useful proteins as possible.

The choice of 45 000 Dalton for the upper limit of the molecular weight of the toxic mediators to be removed was arbitrary, especially because the patent did not explain any reason or technical effect related to this specific value. The ranges of 0 to 45 000 Dalton and of 0.1 to 1 for the sieving coefficient were so broad that it was not credible that they could be associated with a technical effect.

Such an arbitrary choice from many possible solutions to the objective technical problem could not be inventive, as confirmed by established case law.

VII. The respondent's arguments, insofar as they are relevant to the decision, are summarised as follows.

Interpretation of features

The feature of the membrane allowing "passage of molecules having a molecular weight of up to 45 000 Daltons with a sieving coefficient of 0.1-1.0 in

presence of whole blood" defined in claim 1 required the membrane to allow the passage of a molecule of 45 000 Dalton with a sieving coefficient of at least 0.1. This meant that the membrane also allowed the passage of smaller molecules with at least that sieving coefficient.

The definition of the nominal cut-off in water of the membrane in claim 1 of the patent as granted defined a property of the membrane and allowed the suitability of the membrane for a particular application of therapy to be assessed. Hence, it had technical character and should be duly considered in the assessment of novelty and inventive step.

Admissibility of B1

B1 was known to the appellant, which chose not to rely on it against claim 1 of the patent as granted in the proceedings before the Opposition Division. Had the appellant wanted to rely on B1, it could and should have already done so in the first-instance proceedings for appropriate consideration of this document by the Opposition Division in the decision under appeal.

Moreover, B1 was not *prima facie* relevant, as it did not disclose the features of the characterising part of claim 1 of the patent as granted.

Hence, B1 should not be admitted into the appeal proceedings.

Novelty in view of E1

E1 did not disclose a membrane having a sieving coefficient for a molecule of 45 000 Dalton of 0.1

to 1.0 in presence of whole blood. Cytochrom C had a lower molecular weight. The disclosure of a sieving coefficient of 0.1 for molecules with a molecular weight in the range of 500 Dalton to 60 000 Dalton related to the membrane in presence of aqueous solutions and not whole blood.

It followed that the subject-matter of claim 1 was novel over E1.

Inventive step in view of E1

The problem solved by the invention was to provide a membrane which could effectively remove larger molecular weight middle molecules ("toxic mediators") from the blood of a patient, while at the same time avoiding the excessive loss of desirable higher molecular weight molecules such as albumin.

There was a technical effect connected to the claimed distinguishing feature of a sieving coefficient of 0.1-1.0 for molecules of up to 45 000 Dalton in presence of whole blood. This feature was a measure for the performance of the membrane and its ability to let higher molecular weight molecules pass than the membranes from the prior art. Such higher molecular weight molecules included several toxic mediators, which could be efficiently removed.

The prior art did not disclose a membrane with the distinguishing feature. Hence, the Opposition Division had been correct to acknowledge an inventive step.

Reasons for the Decision

1. The invention

The invention relates to a permselective asymmetric hollow fibre membrane for the separation of toxic mediators from blood.

According to the patent, the membrane is useful for treating systemic inflammatory response syndrome (SIRS) and multiorgan system failure (MOSF) (paragraph [0012]), which are dangerous secondary complications possibly deriving from a serious illness, trauma or major surgery (paragraph [0002]).

The success of the treatment, which is normally performed by haemofiltration and may be carried out as continuous renal replacement therapy (paragraph [0062]), depends on the ability to effectively remove from the blood the various host-derived inflammatory toxic mediators (TM) responsible for organ dysfunction.

Haemofiltration membranes used in conventional intermittent haemodialysis for treating renal failure remain deficient in the treatment of MOSF because they are not effective in removing toxic mediators in the upper molecular weight range (paragraph [0004]).

The membrane according to the invention is characterised by parameters expressing its permeability to molecules of different molecular weight.

2. Interpretation of features

The parties dispute how the features relating to the definition of the permeability of the claimed membrane should be interpreted. This is crucial for the analysis of novelty and inventive step.

2.1 The appellant argued that the claimed feature of the membrane allowing "passage of molecules having a molecular weight of up to 45 000 Daltons with a sieving coefficient of 0.1-1.0 in presence of whole blood" was fulfilled by any membrane having the specified sieving coefficient with respect to at least one molecule with a molecular weight in the range of 0 to 45 000 Dalton. This assertion was based on case law concerned with claim definitions of ranges.

The "sieving coefficient" with respect to a certain molecule is defined as the ratio of the concentration of that molecule in the filtrate to the concentration of the molecule in the feed.

For every permeable membrane, smaller molecules pass through the membrane more easily than larger molecules. In other words, the sieving coefficient increases with decreasing molecular weight (as can be seen, for example, in Figures 3a and 3b of the patent). In the field of blood treatment, every permeable membrane has a sieving coefficient that is much greater than 0.1 for molecules of a molecular weight of a few Dalton. This means that the claim feature does not define a range of molecular weights for which the sieving coefficient may or may not be 0.1-1.0. Hence, the appellant's reference to case law relating to ranges is irrelevant in this respect.

The correct technical interpretation is that the membrane must have a sieving coefficient of 0.1-1.0 in presence of whole blood for molecules of 45 000 Dalton, which implies the same for molecules of lower molecular weight.

2.2 The appellant also argued that the claimed feature of the membrane having "a nominal cut-off of 200,000 Daltons, with a sieving coefficient of 0.1, in water" had no technical meaning and was therefore not to be considered for novelty and inventive step. More specifically, the appellant argued that the feature in question only meant that the membrane did not let any very large molecules pass, which was inherent for every membrane.

The Board does not share this view. The parameter defines a membrane property, detected by a measurement in presence of water. The appellant's assertion that every membrane had this property is not substantiated.

It is noted that a sieving coefficient of a membrane for a molecule with a certain molecular weight in presence of water implies that the membrane has a lower sieving coefficient in presence of whole blood (as can also be seen in Figures 3a and 3b of the patent in suit). In other words, the definition of the sieving coefficient in presence of water limits the permeability of the membrane in presence of whole blood, which is the typical working condition of the claimed membrane. This is a technical limitation provided by the membrane feature, which therefore is to be duly considered for novelty and inventive step.

3. Admissibility of B1

The appellant raised objections of lack of novelty and lack of inventive step in view of B1 with the statement of grounds of appeal.

According to Article 12(4) RPBA 2007, which applies by virtue of Article 25(2) RPBA 2020, the Board has the discretionary power to hold inadmissible evidence which could have been presented in the first-instance proceedings. According to established case law, the *prima facie* relevance of the evidence provided may be considered by the Board.

As the appellant also submitted, B1 is a document which was cited and considered in the examination of the application, which led to the grant of the patent.

Hence, B1 was known to the appellant, which chose not to rely on it against claim 1 of the patent as granted in the proceedings before the Opposition Division.

Had the appellant wanted to rely on B1, it could and should have already done so in the first-instance proceedings, in order to obtain a decision on the issues of novelty and inventive step of claim 1 in view of this document, which the Board could have reviewed.

Moreover, B1 does not appear, *prima facie*, to directly and unambiguously disclose a membrane with a sieving coefficient of 0.1-1.0 in presence of whole blood for molecules of 45 000 Dalton. In particular, this cannot be inferred from Figure 3, which is rather schematic in nature.

For this reason, under Article 12(4) RPBA 2007, the

Board does not admit B1 into the appeal proceedings.

4. *Novelty in view of E1*

The appellant argued that the subject-matter of claim 1 lacked novelty over E1.

E1 discloses synthetic separation membranes made from synthetic polymers soluble in ε-caprolactam. On page 6, penultimate paragraph, and claims 4 and 5, E1 discloses membranes which may have a cut-off in a range between 500 and 400 000 Dalton, in particular between 500 and 60 000 Dalton in a water solution containing dextran (page 4, first paragraph).

In the specific examples, E1 discloses membranes which have a sieving coefficient between 0.1 and 1 for Cytochrom C (CC), which has a molecular weight of about 12 000 Dalton (Tables 1 and 2, last column, and page 18, penultimate paragraph).

E1 does not disclose a membrane which has a sieving coefficient of 0.1-1.0 in presence of whole blood for molecules of 45 000 Dalton and, at the same time, a nominal cut-off of 200 000 Dalton, with a sieving coefficient of 0.1, in water.

The appellant argued that the disclosure of the sieving coefficient with respect to Cytochrom C would anticipate the feature of the membrane allowing passage of molecules having a molecular weight of up to 45 000 Dalton with a sieving coefficient of 0.1-1.0 in presence of whole blood. In view of the interpretation of this feature explained in point 2.1 above, this is not the case because the molecular weight of Cytochrom C is well below 45 000 Dalton.

The appellant also argued that E1 disclosed a sieving coefficient of 0.1 for molecules with a molecular weight of up to 60 000 Dalton; however, the passages of E1 to which the appellant referred are general and only concern cut-off values in a water solution and not in presence of whole blood (page 4, first paragraph).

Hence, the subject-matter of claim 1 of the patent as granted is novel (Article 54(1) and (2) EPC) over E1. As a consequence, the ground for opposition of lack of novelty under Article 100(a) EPC does not prejudice the maintenance of the patent as granted.

5. Inventive step in view of E1

As the respondent argued and the patent explains in paragraph [0013], the distinguishing features concerning the sieving properties of the membrane defined in claim 1 over E1 make it possible to remove larger molecular weight middle molecules (which include toxic mediators) from the blood of a patient in an improved manner, while at the same time avoiding the excessive loss of desirable higher molecular weight molecules, such as albumin. This is the technical effect of the distinguishing features. Hence, the appellant's assertion that the distinguishing features had no technical effect and were an arbitrary choice is without merit. Whether a membrane with a sieving coefficient of 0.1-1.0 in presence of whole blood for molecules larger than 45 000 Dalton could remove even more toxic mediators is irrelevant in this respect.

The objective technical problem solved is that of improving the treatment of human patients with systemic inflammatory response syndrome (SIRS) and multiorgan

system failure (MOSF) (also derivable from paragraph [0012] of the patent).

The appellant's argument that the problem was simply to provide an alternative membrane does not take due account of the technical effect of the distinguishing features.

The Board sees no obvious reason why the person skilled in the art would modify the membranes disclosed in E1 and provide them with the distinguishing features, since E1 does not teach these features in relation to the objective technical problem.

Hence, the subject-matter of claim 1 of the patent as granted is inventive (Article 56 EPC) over E1. As a consequence, the ground for opposition of lack of inventive step under Article 100(a) EPC does not prejudice the maintenance of the patent as granted.

6. Since none of the grounds for opposition raised by the opponent prejudices the maintenance of the patent as granted, the Opposition Division correctly decided to reject the opposition according to Article 101(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated