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**Datasheet for the decision
of 9 July 2018**

Case Number: T 1305/15 - 3.3.02
Application Number: 04818557.3
Publication Number: 1685862
IPC: A61M1/18, B01D69/08, B01D69/12,
B01D71/44, B01D71/68
Language of the proceedings: EN

Title of invention:

HOLLOW FIBER MEMBRANE FOR BLOOD PURIFICATION AND BLOOD
PURIFICATION APPARATUS INCLUDING THE SAME

Patent Proprietor:

Asahi Kasei Medical Co., Ltd.

Opponent:

Fresenius Medical Care Deutschland GmbH

Headword:

Zeta Potential of hollow fiber membrane / Asahi Kasei Medical

Relevant legal provisions:

EPC Art. 83

Keyword:

Sufficiency of disclosure - all requests (no) - Ill-defined
parameter not reliably measurable (reasons 4.14-4.17)

Decisions cited:

T 0608/07, T 0815/07, T 0593/09, T 1768/15

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1305/15 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 9 July 2018

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 29 April 2015
revoking European patent No. 1685862 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman M. O. Müller
Members: M. Maremonti
P. de Heij

Summary of Facts and Submissions

- I. The appeal by the patent proprietor (hereinafter "appellant") lies from the decision of the opposition division to revoke the European patent No. 1 685 862.
- II. The following document was among those cited during the opposition proceedings:

D7: SurPASS Analysis Report filed by the opponent on 10.03.2015

The Opposition Division came *inter alia* to the following conclusions:

- (a) Document D7 was not admitted into the proceedings.
- (b) The subject-matter of claim 1 according to the then pending main request and auxiliary requests 1 to 7 did not fulfil the requirements of sufficiency of disclosure.
- III. The main request found not to be allowable by the Opposition Division contains nine claims, the sole independent claim 1 reading as follows:

"1. A hollow fiber membrane for blood purification having an integrally continuous structure from the inner membrane surface to the outer membrane surface, the membrane comprising a hydrophobic polymer and a hydrophilic polymer, and exhibiting a zeta potential on the inner surface thereof of greater than -3.0 mV but less than 0 mV at pH 7.5, when measured using a sample with an embedded resin on the outer side for allowing the electrolyte solution to flow through only the inside of the hollow fiber, and using a 0.001 mol/l potassium chloride aqueous solution as an electrolyte solution, wherein

the hydrophobic polymer is selected from a polysulfone-based resin, polyether sulfone-based resin, polyamide-based resin, polyimide-based resin, polyphenyl ether-based resin, and polyphenylene sulfide-based resin and the hydrophilic polymers is selected from polyvinylpyrrolidone, polyethylene glycol, polyglycol monoester, starch, and their derivatives, and water-soluble cellulose derivatives and combinations of said polymers."

Claims 2 to 7 concern specific embodiments of the membrane of claim 1 while claims 8 and 9 concern a blood purification apparatus comprising the membrane of any of claims 1 to 7.

IV. In its statement setting out the grounds of appeal, the appellant contested the reasoning of the Opposition Division and submitted that the claimed subject-matter was sufficiently disclosed in the contested patent. In this connection, it additionally relied on the following new pieces of evidence:

D8: JP-H-11-90186 A

D8a: English machine translation of D8

D9: JP 2003-265934 A

D9a: English machine translation of D9

D10: JP 2003-102833 A

D10a: Partial English translation of D10

D11: JP-H-10-305218 A

D11a: Partial English translation of D11

D12: Written statement of Ms Kuroda dated 09.09.2015

V. In its reply to the statement of grounds, the opponent (hereinafter "respondent") rebutted the appellant's

arguments and maintained that the subject-matter of claim 1 according to all pending requests was not sufficiently disclosed in the contested patent. It corroborated its arguments by re-filing document D7 (II, *supra*) and by additionally relying on the following new piece of evidence:

D13: Declaration of Dr.-Ing. Torsten Keller

VI. The parties were summoned to oral proceedings. In a communication accompanying the summons, the Board drew the attention of the parties to salient issues that might possibly be debated at the oral proceedings.

VII. In a reply to the Board's communication, the appellant reiterated its arguments and relied on the following new pieces of evidence:

D14: "Kinou-Zairyuu", Vol. 14, No 4, April 1994, page 25 et seq.

D15: "Sanyo Product Topics", No 400, Summer 2000

and the respective English translations of relevant parts thereof, named D14a and D15a respectively.

VIII. In a reply to the Board's communication, the respondent maintained all previous objections and additionally submitted the following new piece of evidence:

D13a: Second declaration of Dr.-Ing. Torsten Keller

accompanied by the annex "Instruction for use Ashai Rexeed - A series dialyzer".

IX. In a further letter submitted in preparation for the oral proceedings, the appellant filed the following additional document:

D16: Extract from the *Encyclopedia of Polymer Science and Engineering*, Second edition, 1988, John Wiley & Sons, pages 312, 792, 793 and 798

X. Oral proceedings before the Board were held on 9 July 2018. During the oral proceedings, the respondent withdrew its request not to admit documents D8 to D12 and D16 into the proceedings.

XI. **Final Requests**

The **appellant** (patent proprietor) requested that the decision under appeal be set aside and the case be remitted to the Opposition Division for further prosecution on the basis of the claims according to the main request or to any of auxiliary requests 1 to 7, all requests as filed before the opposition division by letter of 16 December 2013.

It further requested that documents D14, D15 and D16 be admitted into the proceedings.

The **respondent** (opponent) requested that the appeal be dismissed.

It further requested that documents D7 and D13 be admitted into the proceedings.

XII. The appellant's arguments where relevant for the present decision may be summarised as follows:

- Paragraph [0014] of the contested patent gave clear guidance as to how the zeta potential (hereinafter "ZP") referred to in claim 1 at issue had to be measured.
- In particular, the skilled person would not have any difficulty in performing the *embedding* of the

outer surface of the hollow fibers as prescribed in said paragraph.

- The standard technical knowledge concerning *potting resins* could easily be transferred to the resin used in conjunction with the ZP measurement.
- Indeed, such *potting resins* were generally used to fix the hollow fibers to the housing of hemodialysers by using a technology belonging to the common general knowledge of the skilled person. Documents D8 to D11, D14 and D15 confirmed this.
- The measurement of ZP involved only 1400 ± 50 fibers, i.e. a far lower number of fibers in comparison to hemodialysers, in which a bundle of around 20000 hollow fiber membranes was easily and uniformly covered with a potting resin by using routine technology.
- It was not disputed that the embedding of hollow fibers might involve some penetration of the resin to the inner surface of the membrane as shown in D7 and D13.
- However, paragraph [0014] of the contested patent made clear that only the outer surface of the membrane had to be embedded. D12 confirmed that this could be done by hand by using a spatula.
- None of the experiments reported in documents D7 and D13 was carried out by following the procedure outlined in paragraph [0014] of the patent in suit.
- The ZP depended on the chosen resin, the extent of embedding and the number of fibers. In D7 and D13, none of these parameters were selected in

accordance with the invention, particularly with said paragraph [0014].

- Therefore, the obtained results were of no relevance for the sufficiency of disclosure of the claimed subject-matter. It was however true that in the experiments described in D7 and in the fibers examined in D13, the resin used for embedding the fibers had penetrated to the inner surface of the membrane.
- The skilled person knew that penetration of the resin had to be avoided. If the skilled person were aware of some penetration of the resin, which could easily be determined e.g. by microscope photography, he would immediately select a resin that did not penetrate. Assuming otherwise would contradict basic scientific standards in respect of measurement methods.
- High-viscosity polyurethane or epoxy resins as readily available to the skilled person would avoid penetration. The selection of an appropriate embedding material was clearly part of the common general knowledge of the skilled person and required only routine experimentation. Additionally, faster curing of the resin could also be envisaged in order to avoid penetration.
- All examples of the patent in suit showed that membranes according to the invention could be prepared without any undue burden. Uncertainties regarding the ZP measurement could at most bring about a lack of clarity but not insufficiency.
- In order to establish insufficiency, the burden of proof was upon the respondent, which had however

failed to show that the claimed invention could not be carried out on the basis of the teaching contained in the contested patent and common general knowledge.

XIII. The respondent essentially counter-argued as follows:

- Documents D7 and D13 were highly relevant and therefore should be admitted into the proceedings pursuant to Article 12(4) RPBA.
- These documents clearly showed that by selecting generally known *potting* materials like polyurethane or silicone, the resin penetrated to the inner surface of the membrane and strongly affected the ZP measurement.
- In fact, the ZP of the potting resin was measured rather than that of the inner membrane surface.
- The skilled person was not aware of resin penetration and its influence on the measurement of the ZP.
- Neither paragraph [0014] nor the rest of the contested patent contained guidance as to how penetration of the resin could be avoided.
- The selection of resins having an appropriate viscosity such that on the one hand the whole bundle of fibers was embedded over their whole length but on the other hand no penetration occurred, was not part of the common general knowledge of a skilled person.
- D12 stated that the *embedding* of the outer surface could be done by hand using a spatula. It was totally unclear how such a procedure should be

conducted in practice with a number of fibers as high as 1400.

- Moreover, D12 confirmed that said *embedding* could also be done by means of a centrifugal process. It was, however, completely unclear how penetration of the resin could thereby be avoided.
- The ZP was presented in the contested patent as a crucial parameter for solving the problem underlying the invention. According to case law, if such a crucial parameter could not be reliably measured, this amounted not only to a lack of clarity but also to an insufficiency of disclosure.
- The burden of proving that the invention could be carried out was on the appellant, which had however failed to show that the contested patent contained sufficient information enabling the skilled person to measure the ZP referred to in claim 1 at issue without undue burden.
- The claimed invention was therefore not sufficiently disclosed.

Reasons for the Decision

The appeal is admissible.

Admittance of documents D8 to D12, D14 and D15.

- 1.1 The appellant relied on documents D8 to D12, D14 and D15 for its argumentation concerning sufficiency of disclosure.
- 1.2 The respondent did not object to the introduction of documents D14 and D15 into the proceedings and during

the oral proceedings withdrew its request not to admit D8 to D12 (X, *supra*).

- 1.3 The Board has no reason to call the admittance of the above documents into question, and therefore documents D8 to D12, D14 and D15 are part of the appeal proceedings.

Admittance of documents D7 and D13

2. The respondent requested that documents D7 and D13 be admitted into the proceedings pursuant to Article 12(4) RPBA.

The appellant withdrew its request not to admit these documents, and the Board sees no reasons not to admit them. In fact, during the oral proceedings the appellant no longer contested the results reported therein. The Board therefore decided to admit D7 and D13 into the proceedings.

Admittance of documents D13a and D16

3. D13a and D16 are not relevant to the present decision.

Therefore no decision concerning the admittance of D13a and D16 is needed.

Main request - Claim 1 - Sufficiency of disclosure under Article 83 EPC

4. Claim 1 according to the main request is directed (complete wording under III, *supra*) to a hollow fiber membrane exhibiting "*a zeta potential **on the inner surface** [...] of greater than -3.0 mV but less than 0 mV at pH 7.5*" (emphasis added by the Board).

- 4.1 The respondent objected that the whole patent did not contain sufficient information for the skilled person

to measure said ZP on the inner surface of the membrane.

- 4.2 For the invention to be considered sufficiently disclosed, the person skilled in the art, taking into account the whole disclosure of the patent and common general knowledge, must be able to reliably produce a hollow fiber membrane meeting the parametric requirement (ZP) defined in claim 1 at issue.
- 4.3 The Board acknowledges that the examples reported in the patent in suit (see paragraphs [0046] to [0053]) give details as to the *process conditions* to be applied for producing a hollow fiber membrane according to the invention. The membrane of claim 1, however, is not defined in terms of the process for producing it but rather by means of a parameter, namely the ZP on the inner membrane surface, which is required to fall between 0 and -3.0 mV (III, *supra*). In order to reproduce the membrane of claim 1, a person skilled in the art must therefore be able to reliably verify whether or not the ZP of a produced membrane lies within the claimed range.
- 4.4 Claim 1 specifies that said ZP is "*measured using a sample **with an embedded resin on the outer side** for allowing the electrolyte solution to flow through only the inside of the hollow fiber*" (emphasis added by the Board).
- 4.5 Paragraph [0014] of the opposed patent provides more details of how to measure the ZP. A sample is prepared from 1400 ± 50 hollow fibers having a length of 50 ± 5 mm by embedding the outside surface in the longitudinal direction with a resin, leaving the cut ends open. The sample is set to a zeta potential analyzer and an aqueous electrolyte solution is charged from the

opening of the bundle of hollow fiber membranes to measure the zeta potential, thereby causing the electrolyte to flow through only the inner membrane surface.

- 4.6 Paragraph [0014] gives no details of the procedure for embedding the outer membrane surface. In particular, neither the type of embedding material nor the way in which the latter should be applied to the fibers is mentioned.
- 4.7 The experiments reported in D7 and D13 revealed that by embedding hollow fiber membranes comprising a hydrophobic (polysulfone) as well as a hydrophilic (polyvinylpyrrolidone) polymer, i.e. polymers according to claim 1 at issue, with a conventional resin (polyurethane or silicon), the latter penetrated to the inner membrane surface and strongly affected the ZP measurement.
 - 4.7.1 More specifically, in D7 test membrane modules for measuring the ZP were prepared with polyurethane or silicon embedding resins at constant and varying embedding lengths. It was found that the ZP depended on both the type of embedding resin and the embedding length. It must be concluded that the ZP of the resin was measured (at least partially) rather than the ZP of the inner surface of the membrane. This was not in dispute between the parties.
 - 4.7.2 In D13, the inner surface of a hollow fiber membrane of a commercial dialyzer was examined by electron microscopy both at an area where the membrane was embedded in the potting resin of the dialyzer (D13, figure 2) and at an area where the membrane was not in contact with the potting resin (D13, figure 1). It was found that in the first area the inner membrane surface

was covered by the embedding material, which was absent in the second area. This was also not disputed.

- 4.7.3 The Board acknowledges that the experiments denoted in D7 as PU1 to PU3 (polyurethane embedding resin) and Si1 to Si3 (silicon embedding resin) were carried out on 30 fibers only, whereas paragraph [0014] of the contested patent indicates that 1400 ± 50 fibers were employed (4.5, *supra*). The Board however cannot follow the appellant's argument that the measured ZP should depend on the number of fibers used in the experiments. In fact the appellant during the oral proceedings was unable to provide any plausible explanation for any such dependence. Moreover, D7 also contains experiments performed on 1400 fibers with various embedding lengths (see Series LS-131-1 to LS-131-4). Here, an extrapolation of the obtained ZP to a 100% embedding length (as prescribed in paragraph [0014]) showed a value largely corresponding to the one obtained with the same resin (polyurethane) with 30 fibers at 100% embedding length (cf. D7, figure 4).
- 4.7.4 Hence, the fact that some of the measurements performed in D7 were not done with the number of fibers required by paragraph [0014] of the patent does not prejudice the finding that the material used for embedding the outer membrane surface penetrated through the membrane wall to the inner surface of the membrane.
- 4.8 The type of embedding material therefore plays a decisive role for the ZP values obtained by the measurement. Any penetration of the material to the inner surface must be avoided since it would inevitably compromise the measurement and affect the reliability of the results obtained.

- 4.9 During the appeal proceedings, the appellant consistently argued that the skilled person reading the contested patent, particularly paragraph [0014], would promptly refer to his common general knowledge of *potting* technology, i.e. the technique generally adopted to fix the bundle of hollow fiber membranes to the housing of hemodialysers. Here the fibers are indeed *embedded* in a resin.
- 4.10 For the first time during oral proceedings, however, it admitted that with said conventional *potting*, some resin could penetrate to the inner surface of the membrane as confirmed by D13 (4.7.2, *supra*). The skilled person would be aware of this and would avoid penetration.
- 4.11 In the Board's judgement, when performing the ZP measurement with such conventional resins on a membrane produced according to the contested patent, the skilled person would not necessarily be aware that the resin may have penetrated to the inner surface. In this respect the Board notes that, contrary to what has been submitted by the appellant, there is no evidence either in the contested patent or in other documents on file that a skilled person would systematically verify, e.g. through microscope photography, whether or not penetration has occurred. In fact, resin penetration is not mentioned in any of the documents on file and was only revealed by the experiments of the respondent.
- 4.11.1 Moreover, penetration may occur to different extents depending on e.g. the viscosity of the material, the way it is applied and the curing time. The measured ZP, though affected by the presence of the resin, may still lie in the range prescribed by claim 1 at issue. It

would not, however, be representative of the charges on the membrane inner surface.

- 4.11.2 Should the measured ZP lie outside the claimed range, the skilled person would still not immediately conclude that this was due to resin penetration. In fact, this could well be the consequence of the need to optimise the operating conditions of the membrane production process.
- 4.11.3 Should the skilled person nevertheless realise that resin penetration occurred and did affect the ZP measurement, the appellant had still presented no evidence based on verifiable facts which supported the conclusion that the selection of a material that does not penetrate was part of common general knowledge.
- 4.11.4 Resin viscosity and cure time certainly play a role, but the Board holds that the selection of the appropriate material does not merely require routine experimentation. A high-viscosity material may possibly not penetrate, but would in fact pose other problems, for example during the application of this material to 1400 ± 50 fibers as prescribed by paragraph [0014] of the patent in suit. More specifically, at a high viscosity, the embedding material may not be able to fully embed all fibers on their outer side, so that the embedding is incomplete. In this case, the electrolyte applied to measure the ZP may reach the outer side of the membrane. As a consequence, the results obtained with the measurement would again not reflect the ZP of the inner surface of the membrane.
- 4.12 The Board is thus convinced that the skilled person would not necessarily identify resin penetration as a problem for the ZP measurement. Even if he would be aware of this, the selection of an appropriate

embedding resin would require an extensive research programme, thus posing an undue burden on the skilled person.

- 4.13 As set out above, the results shown in D7 and D13 plausibly demonstrated that the ZP measurement was affected by the resin used to embed the membrane outer surface. These results thus succeeded in shifting the burden of proof to the appellant, which had to demonstrate on the basis of verifiable facts that the skilled person, based on the information contained in the contested patent and using common general knowledge, was able to reliably measure the ZP as required by claim 1 at issue, in particular avoiding resin penetration to the inner membrane surface while fully embedding all membrane fibers on their outer side. For the reasons mentioned above, however, the appellant has not presented any convincing arguments, let alone proof, and so its burden of proof has not been discharged.
- 4.14 The Board is aware that according to case law, uncertainties in the measurement of a parameter do not necessarily amount to an insufficiency objection but may merely represent a hidden clarity objection under Article 84 EPC (T 608/07, reasons 2.5.1-2.5.2). This might be the case for example when no measurement method is specified in the patent and different known methods are available to the skilled person, possibly leading to different results (T 1768/15, reasons 6.5.1-6.5.2).
- 4.15 However, when the claimed parameter (here the ZP) is crucial for solving the problem underlying the invention, the method used to measure it should produce consistent values, such that the skilled person will

know when carrying out the invention whether what he produces will solve the problem or not (T 815/07, reasons 5 and 6).

- 4.16 In the present case, the provision of a ZP on the inner membrane surface lying in the claimed range is presented in the patent in suit as the crucial parameter necessary to solve the technical problem underlying the invention (enhancement of phosphorous-removing performance without impairing antithrombogenicity, see paragraphs [0010], [0013] and [0064]).
- 4.17 Due to the severe lack of information concerning the ZP measurement method mentioned *supra*, the ZP on the inner membrane surface is so ill-defined that the skilled person, when trying to reproduce the hollow fiber membrane according to the contested patent, is at a loss whether or not the produced membrane is able to solve the problem underlying the invention (4.16, *supra*). This poses an undue burden on the skilled person, depriving him of the promise of the invention, and thus amounts to insufficiency of disclosure (T 593/09, reasons 3.6, 3.7, 4.1.4).
5. The Board therefore comes to the conclusion that claim 1 of the main request does not define the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The main request is thus not allowable (Article 83 EPC).

Auxiliary requests 1 to 7 - Claim 1 - Sufficiency of disclosure under Article 83 EPC

6. Claim 1 according to all auxiliary requests 1 to 7 contains the same parametric definition of the hollow

fiber membrane in terms of the ZP on the membrane inner surface as claim 1 of the main request.

7. Since the features added to claim 1 of auxiliary requests 1 to 7 do not concern this parametric definition, all auxiliary requests are not allowable under Article 83 EPC for the same reasons given above in relation to the main request.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



N. Maslin

M. O. Müller

Decision electronically authenticated