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**Datasheet for the decision
of 24 October 2014**

Case Number: T 0773/10 - 3.2.02
Application Number: 07008588.1
Publication Number: 1852136
IPC: A61M1/16, A61M1/34, B01D69/08
Language of the proceedings: EN

Title of invention:

Use of a dialysis membrane for preparing a haemodialysis unit
for reducing blood free light chain concentration

Applicant:

Gambro Lundia AB
The Binding Site Group Limited

Headword:

Relevant legal provisions:

EPC Art. 52(1), 53(c), 54(1), 54(2), 54(5), 112(1)(a)
Vienna Convention on the Law of Treaties (1969) Art. 31

Keyword:

Novelty - (no) - novelty of use (no) -
second (or further) medical use (no)
Referral to the Enlarged Board of Appeal - (no)

Decisions cited:

G 0001/83, G 0005/83, G 0002/08, T 2003/08

Catchword:



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 0773/10 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 24 October 2014

Appellant: Gambro Lundia AB
(Applicant 1) Magistratsvägen 16
22 643 Lund (SE)

Appellant: The Binding Site Group Limited
(Applicant 2) PO Box 11712
Birmingham
B14 4ZB (GB)

Representative: Hornung, Veronika Margot
c/o Gambro Dialysatoren GmbH
Holger-Crafoord-Strasse 26
72379 Hechingen (DE)

Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on
30 September 2009 refusing European patent
application No. 07008588.1 pursuant to
Article 97(2) EPC.**

Composition of the Board:

Chairman E. Dufrasne
Members: D. Ceccarelli
M. Stern

Summary of Facts and Submissions

- I. The applicant has appealed the Examining Division's decision, dispatched on 30 September 2009, to refuse European patent application 07 008 588.1.
- II. In its decision, the Examining Division held that the subject-matter of claim 1 of the main request was not novel. More particularly, the claim had been drafted as a second-medical-use claim in the Swiss-type format, but it defined the use of a device to produce an appliance for medical purposes. It followed that the special approach to the novelty assessment as set out in decision G 1/83 for substances and compositions was not applicable. As a result, the subject-matter of claim 1 was anticipated by the disclosure of document:

D1: WO-A-2004/056460.

- III. Notice of appeal was received on 30 November 2009 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 3 February 2010.
- IV. The Board summoned the appellant to oral proceedings and set out its preliminary opinion in a communication dated 9 July 2014.
- V. By letter dated 24 September 2014 the appellant filed the following documents in support of its arguments:

Enclosure 1: Medical Devices Guidance Document of the European Commission, Classification of medical devices, MEDDEV 2.4/1 Rev.9, June 2010;

Enclosure 2: Proposal for a Regulation of the European Parliament and of the Council on medical devices, 2012/0266 (COD), 26 September 2012;

Enclosure 3: EN ISO 141 55:2011, second edition, 1 February 2011;

Enclosure 4: Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001;

Enclosure 5: Technology Brief: Theralite™ for treatment of renal failure in patients with multiple myeloma, HealthPACT, February 2012.

VI. Oral proceedings took place on 24 October 2014.

VII. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed with letter received on 3 February 2010.

The appellant further requested that, if the Board was minded to dismiss the appeal, the proceedings should be stayed and the following questions should be referred to the Enlarged Board of Appeal in accordance with Article 112(1) EPC:

"1. Can the refusal of purpose-related patent protection for a second or further new therapeutic use of medical device be explicitly based on Articles 54(4) and 54(5)EPC in the light of the decision G 005/83 and/or the travaux préparatoires for the EPC 2000?

2. If Question 1 is answered in the negative, has the concept of patentability of the exception introduced

by Art. 53(c) EPC and Articles 54(4) and (5) EPC for a new and inventive therapeutic application in accordance with the decision G005/83 to be construed broadly and extended to new and inventive therapeutic applications of medical devices?

3. If Question 2 is answered in the positive, which are the patentability requirements for a new therapeutic application of a known medical device?

4. If Question 1 is answered in the positive, what specifically is the basis for refusing purpose-related patent protection under Articles 54(4) and 54(5) EPC to medical devices as contrasted with purpose-related patent protection for medical substances or compositions?

5. If purpose-related product claims for new and inventive therapeutic applications of known medical devices remain excluded under Articles 54(4) and 54(5) EPC in the light of G005/83, are there ways of constructing a claim which provides protection for such new and inventive therapeutic application of a known medical device?"

VIII. Independent claim 1 reads as follows:

"A dialysis membrane for the treatment of multiple myeloma that allows passage of molecules having a molecular weight of up to 45 kDa in presence of whole blood, and has a molecular weight exclusion limit in water of about 200 kDa."

IX. The appellant's arguments may be summarised as follows:

- a) Claim 1 was directed to a new use of a membrane which, as such, had been described before in document D1. A new use of a known medical product reflected a newly discovered technical effect. Attaining such a technical effect should be considered as a functional technical feature of the claim. If such a technical feature had not been previously made available to the public, then the claimed invention was novel.

Article 53(c) EPC, which defined an exception to patentability of certain medical or therapeutic methods, explicitly stated that such an exception did not apply to "products, in particular substances or compositions, for use in any of these methods". A membrane as claimed in claim 1 was undoubtedly a "product" or "substance" for use in a therapeutic method and was not excluded under Article 53(c) EPC. By virtue of Article 54(4) and (5) EPC, an inventor of a new medical use could obtain patent protection. However, in contrast with Article 53(c) EPC, which recognised that products other than substances or compositions could be patentable, Article 54(4) and (5) EPC only referred to "substances or compositions". The reasons for this discrepancy were equivocal and debatable. Exempting the whole class of inventions relating to a new use of known medical products other than substances or compositions from any patent protection resulted in an unjustifiable legal gap.

Patent protection for new medical uses of a known medical product would not obstruct practitioners in their daily duties towards persons and animals in need as it would be subject to the same

principles as medicaments or drugs as commonly defined.

Studying the legislative history which led to the exception as laid down in Article 54(4) and (5) EPC, it was evident that the only focus of the discussions had been on the new uses of compound or "substances", i.e. products of the pharmaceutical industry which would otherwise be referred to as "medicaments" or "drugs", but there was no indication that other medical products had been deliberately excluded from the exception.

For these reasons and also as a matter of legal non-discrimination, the exception introduced by Article 54(4) and (5) EPC for a new and inventive therapeutic application should be broadly construed and should also apply to a product.

That would not unjustifiably extend patent protection to trivial new uses of known medical devices, as this problem was already addressed by the basic requirements of novelty and inventive step and was comparable with the consequences of decision G 2/08, according to which patents could be granted for new therapeutic applications of substances or compositions based on new patient groups to be treated, new technical effects, different dosage regimes or even different modes of drug administration.

As shown in particular in Enclosures 1 to 4, the regulatory landscape for medical devices had changed considerably since decision G 5/83, concerned with second medical uses of substances or compositions, had been taken. Especially

medical devices falling into higher risk classes often required clinical investigations equivalent to those required for drugs. Hence, a narrow interpretation of Article 54(4) and (5) EPC, not providing for patent protection for new uses of known medical devices, should not be applied in the long run and was not justifiable if the aim was to improve public health. The investment required to develop new medical uses of known medical devices was not justified if there was no patent protection for them.

- b) Moreover, specifically for the present case, Enclosure 5 showed that certain limited studies showing the benefit of the new therapeutic use of the claimed membrane had already been conducted. Developing the membrane for such a use had involved an investment in terms of time and costs comparable to that necessary for finding new medical uses of known substances or compositions. It followed that the claimed membrane had to be considered analogous to a substance or composition within the meaning of Article 54(5) EPC.

In decision T 2003/08 the new use of a medical device, a column for extracorporeal treatment, had been deemed patentable because it contained a ligand, a "chemical entity" bonded to the column and being the "active" ingredient responsible for the "therapeutic effect", which was consumed during use. In the present case, the polymeric membrane in its dialyser unit was analogous to the ligand of decision T 2003/08 as, in use, it also removed certain molecules from the blood of a patient and was consumed ("fouling"). More particularly, it performed "the same function as a

drug administered for eliminating free light chains from or inactivating them in the blood stream" and it was "a single-use product which is consumed during use". The contribution of the membrane as an "active" part in delivering a therapeutic effect had therefore to be considered.

Further, the new use of the membrane would contribute to an expansion of the manufacture of such membranes. Hence, also for this reason, the claimed membrane was "perfectly analogous" to a medicament.

It followed that the subject-matter of the claims of the main request was novel in view of Article 54(5) EPC.

It appeared also that the Board might not be competent to decide upon the questions raised in the statement of ground of appeal. Referral to the Enlarged Board of Appeal was therefore appropriate.

Reasons for the Decision

1. The appeal is admissible.
2. The claimed invention

The invention relates to the field of haemodialysis. In particular, it is based on the assumption that removing free light chain molecules (FLCs), which are constituents of immunoglobulins, from blood by haemodialysis might reduce renal failure in patients with multiple myeloma (paragraph [0022] of the

published application).

Claim 1 is directed to a dialysis membrane to be used in a haemodialysis process to effectively reduce blood free light chain concentration in a patient.

3. Novelty

3.1 It is undisputed that document D1 discloses all the structural features of the dialysis membrane according to claim 1. More particularly, page 4, lines 6 to 14 discloses a dialysis membrane that allows passage of molecules having a molecular weight of up to 45 kDa in presence of whole blood, and has a molecular weight exclusion limit in water of about 200 kDa. As also explained in detail in the published application (paragraphs [0026] to [0033]), such a membrane is effective in removing FLCs from whole blood. Hence, the membrane of document D1 is inherently **suitable for** the treatment of multiple myeloma within the meaning of claim 1.

It follows that, as such, the membrane of claim 1 is anticipated by the disclosure of document D1, thereby lacking novelty within the meaning of Article 54(1) and (2) EPC.

3.2 As far as relevant for the present case, Article 53(c) EPC prescribes that:

"European patents shall not be granted in respect of methods of treatment of the human [...] body by [...] therapy [...] practised on the human [...] body; this provision shall not apply for products, in particular substances or compositions, for use

in any of these methods."

In Article 54(4) and (5) EPC it is respectively stated that Article 54(2) EPC:

"shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art",

and

"shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art."

These provisions introduce a special assessment of novelty for purpose-related features.

- 3.3 According to the appellant's submissions, the specific use of the dialysis membrane claimed in claim 1 for the treatment of multiple myeloma, i.e. a method of treatment by therapy of the human body referred to in Article 53(c) EPC, is not comprised in the state of the art.

It is therefore crucial to determine whether the special assessment of novelty set out in Article 54(5) EPC may apply to such a membrane. More particularly, it all boils down to establishing whether the claimed membrane should be considered a "substance or composition" within the meaning of

Article 54(5) EPC.

3.4 The Board identifies two main lines of argument in the appellant's submissions:

- that the expression "substance or composition" in Article 54(5) EPC should be construed broadly and extend to any product for any specific use in a method referred to in Article 53(c) EPC;
- that at least the specific membrane according to claim 1, due to its particular nature, should be considered a "substance or composition" within the meaning of Article 54(5) EPC.

3.4.1 It is hardly disputable that the ordinary meaning of the term "product" is broader than "substance or composition".

Moreover, also the way Article 53(c) EPC is drafted explicitly shows a difference between "product" as a general entity and "substance or composition" as particular examples of that general entity.

The appellant referred to the legislative history which led to the exception as laid down in Article 54(5) EPC, in particular to the "travaux préparatoires" for the EPC 2000, to argue that the legislator's attention focused on the new uses of compounds or "substances", i.e. products of the pharmaceutical industry which are generally referred to as "medicaments" or "drugs", but there was no intention to exclude any other medical products from that exception.

The Board does not question that decision G 5/83 cited by the appellant, which was taken as a basis for the

introduction of new Article 54(5) EPC in the "travaux préparatoires" for the EPC 2000 (in particular MR/18/00 drawn up by the Swiss delegation), focused on new uses of compounds or "substances", i.e. products of the pharmaceutical industry which are generally referred to as "medicaments" or "drugs".

However, applying Article 31 of the Vienna Convention of the Laws of Treaties (1969) to the EPC, as already done by the boards of appeal, in particular in decision G 5/83 (points 1 to 6 of the Reasons), the Board is unable to share the appellant's view.

That article requires that "a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose" (paragraph 1) and that "a special meaning shall be given to a term if it is established that the parties so intended" (paragraph 4).

Showing that the legislative history did not include discussions on new uses of medical products other than compounds or "substances", i.e. products of the pharmaceutical industry which are generally referred to as "medicaments" or "drugs", cannot establish that the legislator intended to include any such products within the meaning of "substance or composition". In order to justify an extension of the ordinary meaning of "substance or composition" to include any product, it would have rather been necessary to prove that the parties to the EPC intended to do so but failed to reflect this in the wording of Article 54(5) EPC.

The appellant's arguments relating to an alleged legal discrepancy or discrimination due to the exemption from

patent protection of the whole class of inventions relating to a new use of known medical products other than substances or compositions may be of general interest but are of little relevance for the present case.

It is simply not the Board's task to draft legal provisions. Hence, it is neither the Board's duty nor its competence to evaluate the arguments about how desirable or equitable patent protection for any medical product may or may not be.

Based on these considerations, the Board comes to the conclusion that the scope of the term "substance or composition" in Article 54(5) EPC does not extend to all products for a specific use in a method referred to in Article 53(c) EPC.

- 3.4.2 As regards the appellant's argument that at least the specific dialysis membrane according to claim 1 should be considered a "substance or composition" within the meaning of Article 54(5) EPC, the Board is unable to share this view.

Whether the membrane could perform "the same function as a drug" is not decisive, since this could equally hold true for any medical device having such a function. However, as already explained above and in accordance with the established case law of the boards of appeal, the provision of Article 54(5) EPC does not apply to all such devices.

The Board also does not regard the claimed membrane as "a single-use product consumed during use". As such, the fact that the membrane can be adversely affected by use, e.g. due to some "fouling", does not exclude a

further use. The function of the membrane could be re-established for example by appropriate treatment.

The appellant also referred to decision T 2003/08, which allowed a claim directed to a new use of a column for an extracorporeal treatment. However, as the appellant also pointed out, in that decision it was not the column as such which was regarded as the "substance or composition" the new use of which could confer novelty according to Article 54(5) EPC. Rather, the column contained a ligand constituting the "active" ingredient responsible for the "therapeutic effect".

In the Board's view, the present case is different. The claimed dialysis membrane does not contain any further substance or composition which may constitute an "active" ingredient according to decision T 2003/08.

The appellant's arguments relating to the costs in terms of time and money for developing the claimed membrane and to special approval requirements for a new use are not decisive either, since they do not directly pertain to the nature of the claimed subject-matter.

3.5 It follows that for the claimed dialysis membrane the exceptional novelty assessment as set forth in Article 54(5) EPC does not apply.

Hence, the subject-matter of claim 1 is not patentable under Article 52(1) EPC, since it lacks novelty within the meaning of Article 54(1) and (2) EPC.

For this reason, the application is to be refused.

4. *Request for referral to the Enlarged Board of Appeal*

According to Article 112(1)(a) EPC, "in order to ensure uniform application of the law, or if a point of law of fundamental importance arises[,...] the Board of Appeal shall, during proceedings on a case [...] following a request from a party to the appeal, refer any question the the Enlarged Board of Appeal if it considers that a decision is required".

In the present case, the Board is not aware of - and the appellant has not shown - any divergence in the jurisprudence of the boards of appeal.

Moreover, the Board does not consider a referral necessary, as it is in a position to confidently decide upon the issues raised in the grounds of appeal, as apparent from the reasons given above. There is no need for the Board to answer the questions submitted in general or even simply broader terms.

The request for referral to the Enlarged Board of Appeal is therefore refused.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated