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Datasheet for the decision of 12 November 2014

Case Number: T 2392/10 - 3.2.02

Application Number: 02730586.1

Publication Number: 1395311

IPC: A61M1/36

Language of the proceedings: EN

Title of invention:
METHOD FOR FILLING AND WASHING A FILTER FOR A DIALYSIS MACHINE

Patent Proprietor:
Gambro Lundia AB

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 69, 83, 111(1), 123(2), 123(3)
EPC R. 43(3)

Keyword:
Sufficiency of disclosure - (yes)
Amendments - added subject-matter (no) -
broadening of claim (no)
Appeal decision -
remittal to the department of first instance (yes)

Decisions cited:
G 0001/93, T 0582/91, T 0461/05

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

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 2392/10 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 12 November 2014

Appellant: (Patent Proprietor)	Gambro Lundia AB Magistratsvägen 16 22 643 Lund (SE)
Representative:	Ponzellini, Gianmarco Ponzellini, Gioia e Associati S.r.l. Via Mascheroni, 31 20145 Milano (IT)
Respondent: (Opponent)	Fresenius Medical Care Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg (DE)
Representative:	Bobbert, Cornelius Bobbert & Partner Patentanwälte PartmbB Postfach 86 06 28 81633 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 26 October 2010 revoking European patent No. 1395311 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The patent proprietor has appealed the Opposition Division's decision, dispatched on 26 October 2010, to revoke European patent No. 1 395 311.

II. The Opposition Division revoked the patent on the grounds that claim 1 of the amended main, and first and second auxiliary requests then on file contained "an intermediate generalisation" leading to a breach of Article 123(2) EPC. Moreover, the third and fourth auxiliary requests, filed during the oral proceedings before the Opposition Division, were not admitted under Article 114(2) EPC.

III. The notice of appeal was received on 7 December 2010 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 7 March 2011.

IV. The respondent replied to the statement of grounds on 25 July 2011.

V. The Board summoned the parties to oral proceedings and provided its provisional opinion in a communication dated 9 July 2014.

VI. Oral proceedings took place on 12 November 2014.

VII. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request filed with letter dated 4 March 2011 or, in the alternative, of one of auxiliary request 1 filed with letter dated 10 October 2014, auxiliary request 2 filed with letter dated 4 March 2011, and auxiliary request 3 filed with

letter dated 10 October 2014.

It also requested a remittal to the department of first instance for examination of novelty and inventive step, should the Board come to the conclusion that a request complied with the other requirements of the EPC.

VIII. The respondent requested that the appeal be dismissed.

It also requested that auxiliary requests 1 and 3 should not be admitted into the proceedings and that the case be remitted to the department of first instance before any examination of novelty and inventive step by the Board.

IX. The following documents are mentioned in the present decision:

D3: EP-A-0 992 255;
D5: EP-A-0 560 368.

X. Claim 1 of the main request, which corresponds to the main request considered in the impugned decision, reads as follows:

"Method of filling and washing a filter (4) of a dialysis machine (1), the machine comprising a dialysate circuit (3), a blood circuit (2) and a filter (4) comprising a dialysate compartment (6) connected to the dialysate circuit (3), a blood compartment (5) connected to the blood circuit (2), and a semi-permeable membrane (7) to separate the dialysate compartment (6) from the blood compartment (5), the method comprising:

a - recirculating a physiological saline in the

dialysate circuit (3) in such a way that the dialysate compartment (6) is filled and washed with the physiological saline;

b - closing the blood circuit (2) to form a loop, the blood compartment (5) and the blood circuit (2) being in communication with the external environment;

c - generating a pressure difference between the dialysate compartment (6) and the blood compartment (5) in such a way that some of the physiological saline is transferred from the dialysate compartment (6) into the blood compartment (5) through the membrane (7);

d - filling of the blood circuit (2) with the physiological saline, which is transferred through the membrane (7);

e - recirculating the physiological saline in the blood circuit (2) by means of a peristaltic pump (16)."

XI. As far as relevant for the present decision, the appellant's arguments may be summarised as follows:

a) Article 123(2) EPC

Claim 1 of the main request derived from a combination of originally filed claims 1, 2, 5, 6 and 9. Originally filed claim 5, however, depended on claims 3 and 4, the subject-matter of which was not present in claim 1 of the main request. For this reason, according to the impugned decision, claim 1 contained an "intermediate generalisation".

According to the long and well-established case

law of the boards of appeal, an amendment to a patent fulfilled the requirements of Article 123(2) EPC if, for the skilled person, the overall change in the content of the application was directly and unambiguously derivable from what had previously been presented by the application. The EPC did not mention the concept of "intermediate generalisation", which had rather been defined by the boards of appeal.

In this context, in decision T 461/05 it was held that a restriction of a claim by adding a number of features from a particular embodiment originally disclosed did not in itself introduce new information not following directly and unambiguously from the application as originally filed. By contrast, the omission of the remaining features of the embodiment would introduce new information if the omitted features were necessary to carry out the particular embodiment of the invention. Similarly, in decision T 582/91, it was held that one feature of a dependent claim could be readily combined with a preceding independent claim as long as the skilled person recognised that there was clearly no close functional or structural relationship between the one feature of that dependent claim and its other features, or between that one feature and the teaching of other dependent claims referred to in that dependent claim.

In the present case, for the feature "the blood compartment (5) and the blood circuit (2) being in communication with the external environment" there was a basis in column 3, lines 1 to 3 and 25 to 30; column 4, lines 2 to 5 and claim 5 of the

granted patent, which corresponded to respective passages of the application as filed.

Moreover, claim 1 of the main request was not "new" over the original application and hence passed the so-called novelty test.

The circulation of the physiological saline at two pressures according to original claims 3 and 4 did not have any structural or functional relationship with the blood compartment and the blood circuit being in communication with the external environment. The invention was about priming an extracorporeal blood circuit using physiological saline as a priming solution. The physiological saline was transferred from the dialysis liquid circuit into the extracorporeal blood circuit though the membrane of the filter, and air present in the extracorporeal blood circuit was eliminated. For this transfer to take place it was sufficient that the pressure in the dialysis compartment be higher than the pressure in the blood compartment of the filter. The fact that the pressure in the blood compartment of the filter was the atmospheric pressure did not change anything to the above but was only a specific mode of operation.

A skilled person would realise that the core of the patent was to establish a pressure difference between the dialysate compartment and the blood compartment, as described in paragraph [0010]. That pressure difference, which was specified in claim 1 of the main request, was the driving factor for the transfer of the physiological saline to take place. Original claims 3 and 4

related to a preferred embodiment described in detail. Not all the features of this embodiment were essential.

A skilled person would also read the entire original claim set and realise that original claim 7 depended on claim 6 but not on claims 3 and 4. Claim 7 defined a vent tube, thereby implying a communication with the external environment in view of the description of the specific embodiment. This communication had been originally claimed independently from the features of claims 3 and 4. This showed that the features of these latter claims were not essential for the invention.

Claim 1 of the main request did not cover a method in which a suction was created in the blood compartment, because the communication with the external environment would result in a suction of air and no transfer of physiological saline. In particular, the method disclosed in document D5 in relation to figures 4 and 5 was not covered. This method involved a suction of physiological saline from the dialysate compartment but did not take place while the blood circuit was connected to the external environment.

b) *Article 123(3) EPC*

Independent claim 1 of the main request derived from claim 1 as granted, to which several features of a number of dependent claims as granted had been added. Hence, its scope had been limited compared with that of claim 1 as granted. Since the extent of protection conferred by a patent as

referred to in Article 123(3) EPC was defined by the scope of the independent claim, the requirements of that article were fulfilled.

In decision G 1/93 it was not stated that limiting a claim by addition of features might lead to problems in view of Article 123(3) EPC.

c) *Article 83 EPC*

An objection under Article 83 EPC was not admissible, since it would constitute a fresh ground of opposition, the introduction of which required the patent proprietor's consent, which was not given. The patent as granted had not been objected to under Article 100(b) EPC. Although claim 1 of the main request had been amended, the objection was directed to wording already present in claim 1 as granted.

In any event, how to recirculate fluid in a pipe was within the competence of the skilled person.

d) *Rule 43(3) EPC*

Claim 1 according to the main request contained all the essential features of the invention, as identified with the arguments concerning the requirements of Article 123(2) EPC. It followed that Rule 43(3) EPC was complied with.

XII. As far as relevant for the present decision, the respondent's arguments may be summarised as follows:

a) Article 123(2) EPC

At the time of filing of the application, the inventors had neither recognised nor disclosed that the transfer of physiological saline from the dialysate compartment to the blood compartment could be obtained by maintaining a single constant pressure in the dialysate circuit. They had also not realised that a transfer to the blood compartment, the latter being at atmospheric pressure, could also take place if a negative pressure was maintained in the blood compartment, as shown in document D5, column 2, lines 26 to 29. They had only contemplated and disclosed the use of a pressure higher than atmospheric pressure in the dialysate compartment.

Claim 1 according to the main request covered for the first time a transfer method involving the creation of a depression in the blood compartment while having it connected to the atmosphere, as disclosed in document D5, in particular figure 4, column 7, lines 3 to 7 and column 8, lines 16 to 20 and 21 to 26. It also covered for the first time a transfer method involving the use of a single pump and valves in the dialysate circuit, as disclosed in document D3, figure 3. These solutions had not been disclosed in the application as filed.

It followed that adding the features of original claim 5 without the features of original claims 3 and 4 resulted in claim 1 of the main request being in breach of Article 123(2) EPC.

b) Article 123(3) EPC

Claim 1 of the main request comprised the features of claims 1, 2, 5, 6 and 9 as granted. The features of claim 5, however, had only been granted in combination with those of claims 3 and 4. It followed that the subject-matter of claim 1 of the main request extended beyond the granted patent.

In particular, according to the teaching of claim 4 as granted, the elimination of air from the blood circuit in communication with the atmosphere required a second pressure, which caused the transfer of dialysate into the blood circuit, higher than atmospheric pressure. Leaving out this teaching from the subject-matter of claim 1 of the main request resulted in an extension of protection with respect to the granted patent.

Moreover, it was technically feasible to fill the blood compartment of the filter and the blood circuit by maintaining a single constant pressure above atmospheric pressure in the dialysate circuit, for example using a valve as described in document D3. This solution had not been foreseen in the patent as granted. Hence, leaving out the features of granted claim 3 from the subject-matter of claim 1 according to the main request also resulted in an extension of scope of the patent as granted.

Even if the scope of claim 1 as granted was broader than that of claim 1 of the main request, it was doubtful whether that claim had ever

conferred protection, since it was clearly invalid. That was shown by the number of anticipating documents filed during the opposition, which had immediately led to the amendment of the granted claim. According to decision G 1/93 it was the whole content of the patent which had to be considered when assessing whether an amendment resulted in an extension of protection.

In infringement and invalidity proceedings before national courts each claim would be considered independently. Hence, the praxis was different. In view of this, letting the patent proprietor extend the protection conferred by granted claim 5 was unfair towards the other parties to those proceedings.

c) *Article 83 EPC*

According to claim 1 of the main request the invention required a recirculation of physiological saline in the dialysate circuit and in the blood circuit. Those circuits had to be understood as closed circuits. During the recirculations, according to the claim, some of the physiological saline was transferred from one circuit to the other. Such a transfer would hinder both recirculations and was not possible. In any event, the patent did not disclose how it could be done and how the physiological saline could be employed to prime the blood circuit.

d) Rule 43(3) EPC

Claim 1 according to the main request related to the filling of the blood compartment of a closed-loop blood circuit. Since the blood circuit was in communication with the atmosphere, the air present in the blood circuit could only be expelled from the circuit if the pressure in the dialysate circuit was higher than the atmospheric pressure. It followed that the feature of original claim 4 was essential for the invention and could not be left out in view of Rule 43(3) EPC.

Reasons for the Decision

1. The appeal is admissible.

2. The invention relates to the field of haemodialysis and is directed to a method for washing a filter of a dialysis machine.

Such dialysis machines comprise a blood circuit and a dialysate circuit, both connected to a filter including a semi-permeable membrane. During a dialysis treatment, the membrane separates a compartment containing the dialysate from another compartment containing the patient's blood. Unwanted substances in the blood pass through the membrane and are transferred to the dialysate.

Before each treatment is performed, both circuits and the semi-permeable membrane must be "primed" and washed. For this purpose, the invention proposes a particular method "which is simple, economical and requires minimum intervention by the operator" (paragraph [0007]

of the patent as granted).

In particular, the method involves the recirculation of a physiological saline in the dialysate circuit, wherein a pressure difference is generated between the dialysate circuit and the blood circuit, so that part of the physiological saline can pass through the membrane and gradually fill the blood circuit.

3. *Main request - Article 123(2) EPC*

The subject-matter of claim 1 of the main request includes the features defined in claims 1, 2, 5, 6 and 9 as originally filed.

However, claim 5 depended on originally filed claims 3 and 4, the features of which are not comprised by the subject-matter of claim 1 of the main request.

More particularly, the feature as defined in claim 5 that the blood compartment and the blood circuit are in communication with the external environment is included, while the features as respectively defined in claims 3 and 4 that the physiological saline in the dialysate circuit is circulated at a first and a second, greater, pressure to transfer the physiological saline from the dialysate compartment to the blood compartment, and that the second pressure is greater that atmospheric pressure, are not included.

As submitted by the respondent, all these features had been presented in combination by the claims and also in the description of the preferred embodiment of the invention in the application as filed.

It has therefore to be established whether the

introduction of only one of the features of this originally disclosed embodiment in claim 1 of the main request results in subject-matter extending beyond the content of the application as filed, in breach of Article 123(2) EPC.

Amendments of this kind are not unusual and have often been referred to as "intermediate generalisations" by the boards of appeal. The impugned decision also uses that denomination.

The Board notes that the fact that an amendment may constitute an intermediate generalisation does not mean, per se, that the amendment is not allowable. Rather, no matter which particular kind of amendment is to be assessed, according to the established jurisprudence of the boards of appeal ("Case Law of the Boards of Appeal of the European Patent Office", 7th edition 2013, II.E.1), the generally accepted standard is that an amendment is in breach of Article 123(2) EPC if it presents the skilled person with technical information which cannot be derived directly and unambiguously, using common general knowledge, from the application as filed.

In the case at issue it is therefore to be assessed whether leaving out the fact that the physiological saline in the dialysate circuit is circulated at a first and a second pressure, and that the second pressure is greater than atmospheric pressure, while including the feature that the blood compartment and the blood circuit are in communication with the external environment, presents the skilled person with such technical information.

In the Board's view, in accordance with the conclusion

of decision T 461/05 (point 2.4 of the reasons), the omission of certain features of an originally disclosed embodiment, for example the preferred embodiment of the invention, would introduce such technical information if the omitted features were technically necessary, i.e. inextricably linked with the introduced features, for the functioning of that embodiment. In such a case, the omission would present the skilled person with the new information that, contrary to what had originally been disclosed, the omitted features were not technically necessary for that functioning.

From the originally filed application as a whole, the skilled person is presented with the general idea that "some of the [...] physiological saline is transferred from the dialysate compartment [...] to the blood compartment [...] through the [...] membrane" (claim 1). A method is thereby obtained, which is "simple, economical and requires minimum intervention by the operator" (page 2, lines 9 to 12 and page 2, line 27 to page 3, line 4).

According to the application as filed, in order for this transfer to take place, a pressure difference between the dialysate compartment and the blood compartment is necessary (page 3, lines 5 to 10).

From a technical point of view, however, sequentially producing two pressures P1 and P2 as described on page 4, line 23 to page 5, line 5 and claimed in claim 3 of the original application is neither necessary nor has it got anything to do with the transfer of the physiological saline through the membrane when the blood compartment and the blood circuit are in communication with the external environment. Based on the general teaching of the

application as filed, the skilled person would recognise that producing such pressures is merely one of several generally known options, for achieving the transfer, independent of the fact that the blood compartment and the blood circuit are in communication with the external environment or not. Rather, as long as a pressure difference between the dialysate compartment and the blood compartment within the meaning of the original application is maintained, any pressure profile would do.

As regards the omitted feature that the physiological saline should be circulated at a second pressure being greater than atmospheric pressure, as claimed in original claims 3 and 4, the Board notes that such a pressure is also not essential for the transfer to take place, even under the condition that the blood compartment and the blood circuit are in communication with the external environment. The skilled person generally knows that, in a hydraulic circuit, a connection with the external environment does not necessarily result in a constant atmospheric pressure everywhere in the circuit. In actual fact, especially under non-steady conditions, this will be the exception, due to the intrinsic flow resistance of the various components of the circuit. Again, as long as a pressure difference between the dialysate compartment and the blood compartment within the meaning of the original application was maintained, any pressure level would do. The skilled person would readily recognise that circulating the physiological saline at a pressure greater than atmospheric pressure is merely an option and that, under particular conditions, the necessary pressure could be lower. Incidentally, under the condition that the pressure in the blood compartment is the atmospheric pressure, the pressure in the dialysate

compartment should be higher. However, this is already required by claim 1 of the main request.

The fact that original claim 7 defining a vent tube depended on claim 6 but not on claims 3 and 4, as pointed out by the appellant, also hints at the optional character of the features of those claims 3 and 4, even under the condition that the blood compartment and the blood circuit are in communication with the external environment. According to the description of the specific embodiment of the invention in the original application, the vent tube establishes such communication (page 5, lines 24 to 31), which is then also to be considered technically independent of the features of claims 3 and 4 as originally filed.

The respondent also argued that claim 1 of the main request covered for the first time specific transfer methods, such as the ones mentioned in relation to documents D3 and D5, which had neither been recognised nor disclosed by the inventors at the time of filing of the application.

However, the Board notes that what is covered or not covered by an amended claim is not necessarily decisive in the assessment of its compliance with Article 123(2) EPC. Generally, claims are drafted in order to obtain protection for a general inventive matter, thus covering more than the specific embodiments disclosed in the application. In case of an intermediate generalisation based on an originally disclosed embodiment, the scope of protection of the resulting amended claim will inevitably extend beyond that specific embodiment. What has rather to be assessed is what is disclosed by the amended claim, which should then be compared with the original

disclosure as a whole. For the present case, while it may be agreed that the original application did not directly and unambiguously disclose the specific embodiments of documents D3 and D5 as explained by the respondent, it is also to be noted that amended claim 1 according to the main request does not disclose such specific embodiments either. Hence, no new information is presented to the skilled person even in this respect.

For these reasons the Board comes to the conclusion that the subject-matter of claim 1 of the main request does not present the skilled person with any information not directly and unambiguously derivable, using common general knowledge, from the application as originally filed.

The dependent claims directly derive from respective claims of the application as originally filed.

Hence, the requirements of Article 123(2) EPC are fulfilled by the main request.

4. *Main request - Article 123(3) EPC*

As the appellant argued, independent claim 1 of the main request derives from claim 1 of the patent as granted, to which several features of a number of dependent claims as granted have been added. Hence, its scope is limited compared with that of claim 1 of the patent as granted.

In the present case the Board is of the opinion that claim 1 of the patent as granted defined the broadest scope of protection, since all the other claims were dependent on it and defined further additional features

which, also individually, remained within its general scope.

In this context, whether the features of claim 5 had only been granted in combination with those of claims 3 and 4, as the respondent argued, is of no relevance, since the protection conferred by the patent as granted already extended to the broader method defined in claim 1, which was not limited by any of those features.

The respondent's argument that claim 1 of the patent as granted was clearly invalid and, hence, it was doubtful whether it had ever conferred protection, cannot be followed.

As also explained in decision G 1/93 cited by the respondent (points 9 to 11 of the reasons), the provisions of Article 123 EPC protect the interests of third parties before a final version of the patent, if any, is issued by the EPO. During this time, the third parties should be able to firstly rely on the content of a patent application as filed and published and then, if applicable, on the scope conferred by the granted patent. These provisions are in addition to the requirement of validity of the claims, but are wholly independent of it. In this context, Article 69(2) EPC, which governs the extent of protection within the meaning of the EPC, even refers to the protection conferred by a European patent application, which is already given before any examination as to validity is started.

As to the respondent's considerations concerning infringement and invalidity proceedings before national courts, the Board sees them as irrelevant, as they are

not related to the explained purposes of Article 123(3) EPC either.

For these reasons the Board concludes that the main request complies with Article 123(3) EPC.

5. *Main request - Article 83 EPC*

In the Board's view, the respondent's objection as to insufficiency of disclosure of the invention according to claim 1 of the main request does not succeed.

How the method according to claim 1 of the main request is carried out is explained in detail in paragraph [0017] of the patent. In particular, the fact that some physiological saline can move from one circuit to the other directly derives from the claimed pressure difference. How to obtain and maintain it is within the common general knowledge of the person skilled in the art, especially considering the disclosure of the specific communication between the blood circuit and the atmosphere, such that the transferred physiological saline can replace the air by pushing it out of the circuit, and the continuous supply of physiological saline to the dialysate circuit by means of device 24 (column 3, lines 15 to 18 and the figure of the granted patent).

Hence, at least for this reason, the provision of Article 83 EPC does not constitute a bar to patentability of the main request.

6. *Main request - Rule 43(3) EPC*

The Board notes that the respondent's arguments supporting the objection under Rule 43(3) EPC are

strictly related to those presented in relation to the requirements of Article 123(2) EPC. More particularly, the respondent considered that the omitted features of claims 3 and 4 as originally filed were essential within the meaning of that rule for the invention according to claim 1 of the main request.

However, the Board has already explained in point 3 above that it considers those features merely optional. It follows that all the essential features of the invention according to claim 1 of the main request are duly defined in that claim.

Hence, the main request also complies with Rule 43(3) EPC.

7. Under Article 111(1) EPC, following the examination as to the allowability of the appeal, it is left to the Board's discretion whether or not to exercise any power of the department which was responsible for the decision appealed, or remit the case to that department for further prosecution.

Since both parties requested a remittal and in order for them to possibly have the case examined by two instances, the Board decides to remit the case to the Opposition Division for further prosecution.

Since the main request has already been found to comply with the provisions of the EPC examined so far, it is not necessary for the Board to assess the admissibility of the auxiliary requests at this stage.

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 for further prosecution.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated