

Internal distribution code:

- (A) [-] Publication in OJ
- (B) [-] To Chairmen and Members
- (C) [-] To Chairmen
- (D) [X] No distribution

**Datasheet for the decision
of 22 September 2017**

Case Number: T 0430/13 - 3.2.02

Application Number: 02773116.5

Publication Number: 1434646

IPC: B01D61/32

Language of the proceedings: EN

Title of invention:

METHOD AND APPARATUS FOR CONTROLLING A DIALYSIS APPARATUS

Patent Proprietor:

Gambro Lundia AB

Opponent:

Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:

EPC Art. 54(1), 54(2), 56, 104(1), 111(1)

EPC R. 41(2)(c), 76(2)(a), 77(2)

RPBA Art. 12(1), 12(2), 12(4)

Keyword:

Admissibility of opposition - (yes)

Evidence filed with the statement of grounds - could have been
filed in first instance proceedings (no), admitted (yes)

Remittal to the department of first instance - (no)

Apportionment of costs - (no)

Novelty - (yes)

Inventive step - (yes)

Decisions cited:

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 0430/13 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 22 September 2017

Appellant: Gambro Lundia AB
(Patent Proprietor) Box 10101
220 10 Lund (SE)

Representative: J A Kemp
14 South Square
Gray's Inn
London WC1R 5JJ (GB)

Appellant: Fresenius Medical Care Deutschland GmbH
(Opponent) Else-Kröner-Strasse 1
61352 Bad Homburg (DE)

Representative: Herrmann, Uwe
Lorenz Seidler Gossel
Rechtsanwälte Patentanwälte
Partnerschaft mbB
Widenmayerstraße 23
80538 München (DE)

Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
7 December 2012 concerning the maintenance of
European patent No. 1434646 in amended form.

Composition of the Board:

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

Summary of Facts and Submissions

- I. The patent proprietor and the opponent have appealed the Opposition Division's decision, dispatched on 7 December 2012, that European patent No. 1 434 646 could be maintained as amended according to the then pending second auxiliary request.
- II. The notice of appeal of the appellant proprietor (hereinafter the "proprietor") was received on 15 February 2013. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 5 April 2013.
- III. The notice of appeal of the appellant opponent (hereinafter the "opponent") was received on 15 February 2013. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 17 April 2013.

With the statement of grounds, the opponent filed the following documents:

- D9: "AK 200 ULTRA Innovation" - Commercial Brochure, Gambro Medizintechnik GmbH;
D10: Affidavit - Mr Jörg Dreyhsig, 14 April 2013;
D12: "AK 200 ULTRA Gebrauchsanweisung", Rev. 08.1996.

It also referred to D11 as the prior use of the machine Gambro AK 200 ULTRA.

- IV. Oral proceedings took place on 22 September 2017.
- V. The proprietor requested that the appeal of the opponent be dismissed.

During the oral proceedings the proprietor withdrew the main request and the first to third auxiliary requests, filed with letter dated 5 April 2013, and the fourth and fifth auxiliary requests, filed with letter dated 22 August 2017.

The proprietor maintained a procedural request made in the written proceedings - that the opposition be held inadmissible - without presenting new arguments during the oral proceedings. It also requested that D9 to D12 not be admitted into the proceedings and that, if they were admitted, the case be remitted to the Opposition Division and costs awarded against the opponent.

- VI. The opponent requested that the decision under appeal be set aside and that the patent be revoked.

It had requested in writing that Mr Dreyhsig be heard as a witness if the Board had doubts about availability to the public of D9 before the priority date of the patent.

- VII. The following document is also mentioned in the present decision:

D1: US-A-3,946,731.

- VIII. The only claim of the request held allowable by the Opposition Division, which corresponds to claim 11 of the patent as granted, reads as follows:

"Apparatus for hemodiafiltration or hemofiltration comprising:
a dialysate flow path (5, 8, 44, 48, 46, 70, 61, 64),
a blood flow path (80, 84, 51, 70, 74),
a dialyser (50) having a semi permeable membrane (54),

a first [sic] compartment (52) on one side of said semi permeable membrane coupled into said dialysate flow path and a second compartment (51) on the other side of said membrane (54) coupled in said blood flow path, means (65, 72) for measuring the transmembrane pressure, means (48) for providing a replacement fluid flow at a certain flow rate, means (45, 8, 64, 84) for regulating the transmembrane pressure, means (45, 48, 8, 64) for regulating the replacement fluid flow rate, means (45) for setting and storing threshold values for transmembrane pressure and replacement fluid flow rate, **characterized in** control means (45) for selectively controlling either transmembrane pressure or replacement fluid flow rate, selection means (45) for switching from controlling transmembrane pressure to controlling replacement fluid flow rate, when the replacement fluid flow rate threshold is exceeded and switching from controlling replacement fluid flow rate to controlling transmembrane pressure when the transmembrane pressure threshold, is exceeded."

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

Admissibility of the opposition

The opposition was inadmissible, since in the notice of opposition the nationality of the opponent was not identified. It followed that the requirements of Rule 41(2)(c) EPC were not met. The notice of opposition merely provided an address in Germany.

However, an address was different from a nationality.

Admissibility of D9 to D12

D9 to D12 had been filed late for no apparent reason, since they had been cited only with respect to the independent apparatus claim, which had not been amended since the patent had been granted. They could have been filed much earlier, since the opponent had been aware of them since at least 2001. D12 was extremely long; so admitting it into the proceedings would place an unreasonable burden on both the proprietor and the Board. D12 was not properly dated either. A footer including the wording "Rev. 08.1996" did not prove that D12 was publicly available before the priority date of the patent. Its technical content was even in contradiction with the actual technical capabilities of the machine AK 200 ULTRA, sold by the proprietor. Moreover, D9 to D12 were not relevant, since they did not disclose the features of the characterising portion of the claim. For these reasons the Board should exercise its discretion according to Article 12(4) RPBA by not admitting D9 to D12. If the Board did admit them, the case should be remitted to the Opposition Division and costs awarded against the opponent.

Novelty

The subject-matter of the claim was novel. In particular, D12 did not disclose the characterising portion.

The claim required the apparatus to be programmed and configured to automatically switch between controlling transmembrane pressure and controlling replacement fluid flow rate when respective thresholds were

exceeded. That was clear from the definition of the control means and the "when" statement at the end of the claim. Such an interpretation was also in line with the teaching of the patent and the problem it was intended to solve, i.e. avoiding alarms. The automatic switch distinguished the claimed subject-matter from an apparatus like the one of D12, with which the possibility of switching was not automatic but merely given over to the user by providing a selection button.

Inventive step

Starting from D12 as the closest prior art, the features of the characterising portion of the claim solved the problem of reducing alarm situations during the operation of an apparatus for hemodiafiltration or hemofiltration. The only teaching relating to this problem provided by D12 was an appropriate set-up of the apparatus. It had to be accepted that the treatment lasted longer. The skilled person willing to solve the problem stated above would not consider D1 at all, as its teaching went in the opposite direction, i.e. that during a hemodialysis treatment - not hemodiafiltration or hemofiltration - many parameters should be monitored and corresponding alarms should be provided if any of them exceeded its preselected limit. The apparatus performing the treatment should be controlled in such a way that no alarm situations occurred. That was done by trying to keep all monitored parameters within their prescribed limits. The passage in column 6, lines 64 to 67, provided an example of such a control.

Even if one were to start from D1 as the closest prior art, D1 did not disclose any switching from controlling one parameter to controlling another one when respective thresholds were exceeded. There was no

reason why the skilled person would implement such switching in the apparatus of D1 in view of the problem formulated above.

It followed that the subject-matter of the claim was inventive.

X. The opponent's arguments may be summarised as follows:

Admissibility of the opposition

The first page of the notice of opposition comprised the address of the opponent in Germany. The opponent was a German company in the form of a GmbH.

Even if it had not been possible to identify the nationality of the opponent from the notice of opposition, this, per se, would not have resulted in the opposition being inadmissible. Rather, the Opposition Division would have had to communicate this to the opponent under Rule 77(2) EPC.

Admissibility of D9 to D12

D9 to D12 related to a dialysis machine "Gambro AK 200 ULTRA" mentioned in paragraph [0003] of the patent, based on which the opponent had raised an objection of lack of novelty. The Opposition Division had dismissed that objection on the ground that the same paragraph mentioned an operating manual of that machine dated 2002, which was after the priority date of the patent.

D9 was a commercial brochure for the dialysis machine mentioned in the patent in suit, distributed during an exhibition in Ulm that took place from 1 to

3 March 2001. D10 was an affidavit by Mr Dreyhsig, confirming the above. D11 denoted the prior use of that machine. D12 was an operating manual for the same dialysis machine dated 1996, i.e. five years before the priority date of the patent, distributed together with the machine. D12 and the prior use of the dialysis machine "Gambro AK 200 ULTRA" (D11) were highly relevant. Moreover, since they related to a device belonging to the proprietor, their introduction could not constitute an undue burden for it. Hence they should be admitted into the appeal proceedings.

Novelty

Only one objection based on D12 was maintained during the oral proceedings.

D12 disclosed an apparatus for hemodiafiltration or hemofiltration comprising all the features of the claim. It had to be noted that the claim defined an apparatus and not a method. The characterising portion did not specify how the control means for selectively controlling either transmembrane pressure or replacement fluid flow rate were built. In particular, the claim did not specify any automatic switch from controlling the one to the other of these two parameters. The "when" statement at the end of the claim did not specify that the selection means were adapted to switch only when a given threshold of the controlled parameter was exceeded. It followed that any means suitable for controlling both parameters and permitting some switch of control anticipated the claimed control and selection means. The apparatus of D12 could be operated in two different modes ("Druckkontrolle" and "Volumenkontrolle", pages 3:20 to 3:21), respectively controlling the transmembrane

pressure and the replacement fluid flow rate. During a treatment a user could change from the one to the other mode of operation by acting on a specific button (page 3:4). When a threshold of the parameter under control in the active mode of operation was exceeded the apparatus gave an alarm. Hence, the user was advised to change the mode of operation, which resulted in switching between the modes of operation as defined in the claim.

Inventive step

The only objections maintained during the oral proceedings were starting from D12 in combination with D1 and starting from D1 in view of the common general knowledge.

Starting from D12 as the closest prior art, in view of the problem of reducing alarm situations the skilled person would turn to D1, which disclosed a dialyser with a controller that switched from controlling pressure to controlling fluid flow when the pressure exceeded a certain limit (column 6, lines 60 to 67, and claim 29). Hence, D1 taught an automatic control switch between two parameters, aimed at reducing alarm situations. The skilled person would apply the teaching of D1 to the control of the parameters of D12, thereby arriving at the subject-matter of the claim in an obvious way.

D1 taught to control and adjust several parameters during a dialysis treatment in order to avoid alarm situations (claim 1 in column 14, lines 27 to 34). The choice of the specific parameters as defined in the claim was within the competence of the skilled person.

Reasons for the Decision

1. The appeals are admissible.
2. Admissibility of the opposition

The proprietor argued that the opposition was inadmissible, since in the notice of opposition the nationality of the opponent was not identified.

By reference to Rule 41(2)(c) EPC, Rule 76(2)(a) EPC prescribes that the notice of opposition must contain the nationality of the opponent. According to Rule 77(2) EPC, if the Opposition Division notes that Rule 76(2)(a) EPC is not complied with, it must communicate this to the opponent and "invite him to remedy the deficiencies noted within a period to be specified".

The Opposition Division did not send any communication under Rule 77(2) EPC, but decided that the opposition was admissible, complying in particular with Rule 76(2)(a) EPC.

In the appeal proceedings, in its reply to the proprietor's statement of grounds, the opponent endorsed the Opposition Division's conclusion and explicitly stated that it was a German company in the form of a GmbH. If there was a deficiency as argued by the proprietor, the opponent would have remedied it at least by its statement, before any communication under Rule 77(2) EPC was sent. As a result, Rule 76(2)(a) EPC is complied with and the opposition is admissible.

3. Admissibility of D9 to D12

- 3.1 According to Article 12(1), (2) and (4) RPBA, the Board is to take into account all the evidence presented with the statement of grounds of appeal, while retaining discretion to hold inadmissible evidence which could have been presented in the first-instance proceedings.

D9 to D12 were introduced by the opponent in its statement of grounds. The proprietor argued that they could have been filed earlier, since the claim against which they were cited had not been amended since the patent was granted. However, the Board notes that D9 to D12 were introduced in reaction to the Opposition Division's finding that it could not be established which features (if any) of the machine "Gambro AK 200 ULTRA" mentioned in paragraph [0003] of the patent were available to the public before the priority date of the patent. Their introduction has the aim of proving that the structure and functions of that machine belonged to the state of the art. It does not make up a completely new case, but rather constitutes a legitimate attempt by the opponent to improve its position in view of the specific finding of the Opposition Division. The opponent could not reasonably be expected to do so before knowing that finding. This leads the Board to the conclusion that D9 to D12 do not constitute evidence which could have been presented in the first-instance proceedings within the meaning of Article 12(4) RPBA. Hence, under that article, D9 to D12 are part of the appeal proceedings. In this context, the length and technical complexity of D12 are of no relevance to its admissibility.

As regards the proprietor's arguments regarding the technical relevance of D9 to D12 and whether they

belonged to the state of the art, in the present case the Board sees them as a matter of substantive assessment of the evidence. However, they also are of little relevance to the question of admissibility in the given circumstances.

- 3.2 The proprietor requested that the case be remitted to the Opposition Division if the Board admitted D9 to D12.

Under Article 111(1) EPC the Board has the discretion to remit the case or to exercise any power within the competence of the Opposition Division. Considering that the impugned decision has already dealt with novelty and inventive step in view of the other evidence on file, for reasons of procedural economy the Board decides not to remit the case.

- 3.3 The proprietor requested that costs be awarded against the opponent if D9 to D12 were admitted.

Under Article 104(1) EPC each party to the opposition proceedings has to bear its own costs unless reasons of equity require otherwise. The Board does not see any such reasons for ordering a different apportionment. In particular, the opponent cannot be blamed for trying to improve its position in appeal by introducing, at the very beginning of the procedure, together with its statement of grounds, the evidence it considered relevant to its case. Moreover, it is hardly conceivable that the examination of D9 to D12, despite the length of the latter, caused disproportionate costs to the proprietor, since they all concern a machine of a company related to the proprietor.

Hence, each party has to bear the costs it has

incurred.

4. The invention

The invention relates to an apparatus for a hemodiafiltration or hemofiltration treatment comprising, in particular, control means for controlling two specific parameters of the treatment.

In such apparatuses blood from a patient under treatment is conveyed to a compartment of a dialyser, which is separated by a dialysis membrane from another compartment. During the treatment, blood waste and excess water pass through the membrane from the blood compartment to the other compartment and are removed from the patient's blood. The treatment is completed when given quantities of blood waste and excess water have been removed. These correspond to a desired weight loss of the patient. The flow of blood waste and excess water through the membrane is typically called ultrafiltrate liquid flow rate. This flow rate depends, amongst other factors specific to the apparatus in use, on the pressure difference between the blood compartment and the other compartment, i.e. the transmembrane pressure.

Generally, a treatment is optimised by setting thresholds of both the transmembrane pressure and the ultrafiltrate flow rate which ensure the required safety for the patient. By virtue of their interdependence, direct control of one of these parameters results in indirect control of the other. However, the dependency between the ultrafiltrate liquid flow rate and the transmembrane pressure is not constant during the dialysis treatment, due to changes in the patient's blood, which becomes thicker with

time, and in the dialysis membrane, which may partly clog with time.

The invention proposes to control the treatment by direct alternate control - using dedicated pumps and sensors - of the ultrafiltrate flow rate and the transmembrane pressure. The switch from the direct control of one of the two parameters to the other should take place if and when the parameter indirectly controlled exceeds its set threshold. Taking direct control of the parameter beyond its threshold should allow it to be brought back faster to an acceptable level while keeping the other parameter below its own set threshold. The result would be faster treatment ensuring the required safety for the patient.

5. Novelty

It is common ground that D12 discloses an apparatus for hemodiafiltration or hemofiltration comprising all the features of the preamble of the claim.

The apparatus of D12 further comprises control means for selectively controlling either transmembrane pressure or replacement fluid flow rate, since, as the opponent pointed out, it can operate in two different control modes named "Druckkontrolle" and "Volumenkontrolle" (pages 3:20 to 3:21), respectively controlling the transmembrane pressure and the replacement fluid flow rate. D12 also discloses selection means for switching between these control modes. More specifically, these selection means may be in the form of dedicated buttons (third and fifth paragraphs on page 3:4) operated by a user.

D12 does not disclose that the selection means are for

switching from controlling transmembrane pressure to controlling replacement fluid flow rate when the replacement fluid flow rate threshold is exceeded and switching from controlling replacement fluid flow rate to controlling transmembrane pressure when the transmembrane pressure threshold is exceeded.

The Board shares the proprietor's view that those "when" statements are enough to provide the functional limitation that, in its intended state of operation, the apparatus itself reacts to defined conditions related to stored threshold values of the two parameters concerned, switching between modes of operation upon reaching such conditions. In other words, the switching has to be automatic. This is not the case in the apparatus of D12, with which the switching can only take place upon user intervention. This interpretation of that claim wording is consistent with the disclosure of the patent, for example column 4, lines 39 to 43 and lines 50 to 53, according to which the control unit will switch from controlling one parameter to controlling the other.

Even if literally possibly correct, the opponent's view that any means suitable for controlling both parameters and permitting some switch of control anticipated the feature defined by those "when" statements not only ignores the context of the patent as set out in the description, but also assigns no technical meaning to those statements in the claim. In the Board's view such a literal interpretation does not reflect how a claim is understood by the skilled person. The latter tries to give a technical meaning to all the recited features. Clearly, this technical meaning cannot be in contradiction, but has to be backed up by the disclosure of the invention as presented in the patent.

As shown, this is the case for the proprietor's interpretation.

As regards the opponent's argument that the claim was directed to an apparatus and not to a method, the Board notes that, in the present case, employing functional features in an attempt to limit the scope of the apparatus claim is both allowable and adequate.

Lastly, whether the apparatus disclosed in D12 provides an alarm when a threshold of the parameter under control in the active mode of operation is exceeded is irrelevant, because there is neither a disclosure nor an implicit link between such an alarm and automatic switching of the mode of operation.

Hence, the subject-matter of the claim is novel over D12 (Article 54(1) and (2) EPC).

6. Inventive step

6.1 The opponent argued that the subject-matter of the claim was not inventive starting from D12 in combination with D1.

As explained above, the subject-matter of the claim differs from the disclosure of D12 in that the selection means are for switching from controlling transmembrane pressure to controlling replacement fluid flow rate when the replacement fluid flow rate threshold is exceeded and switching from controlling replacement fluid flow rate to controlling transmembrane pressure when the transmembrane pressure threshold is exceeded.

This distinguishing feature has the effect of quickly

resolving alarm situations occurring because either the transmembrane pressure or the replacement fluid flow rate exceeds its respective threshold, by taking direct control of the parameter causing the alarm.

As a result, the hemodiafiltration or hemofiltration treatment can be performed with at least one of the controlled parameters always close to its set threshold, without causing an excessive number of alarm situations (derivable from paragraph [0004] of the patent). It follows that the objective technical problem solved is to minimise the length of the hemodiafiltration or hemofiltration treatment while ensuring the required safety of the patient, rather than reducing alarm situations as such, as argued by the opponent.

D1, referred to by the opponent, discloses an apparatus for treating blood in which a number of parameters are monitored in order to ensure safe functioning. More particularly, the apparatus could be used for hemodialysis, and one monitored parameter could be the ultrafiltrate flow rate (column 4, lines 23 to 35). Another monitored parameter could be the transmembrane pressure (column 7, lines 44 to 49). Generally, the apparatus comprises a fail-safe monitor which may halt the circulation of blood if any of the monitored parameters is outside a predetermined range (column 4, lines 12 to 17 and 23 to 35, and column 8, lines 58 to 62). Upon detection of some anomalies in relation to certain parameters the apparatus may be made to adjust some variables to bring those parameters back within an acceptable range. Claim 29 and column 6, lines 64 to 67, mentioned by the opponent, disclose that upon detection of a drop in the blood pressure of a patient under treatment the apparatus may reduce the

ultrafiltrate flow rate by acting on a pump.

By monitoring and controlling many parameters of the blood treatment, D1 is mainly concerned with increasing the patient's safety. The objective technical problem identified above is not addressed.

Hence, in view of that problem, the skilled person would not have any hint to combine the teaching of D1 with that of D12. If, for any reason, it were to do so, the Board notes that D1 does not even disclose the specific selection means claimed, for switching from controlling transmembrane pressure to controlling replacement fluid flow rate when the replacement fluid flow rate threshold is exceeded and switching from controlling replacement fluid flow rate to controlling transmembrane pressure when the transmembrane pressure threshold is exceeded. In conclusion, the subject-matter of the claim is not obvious starting from D12 in combination with D1.

- 6.2 The opponent further argued that the subject-matter of the claim was not inventive starting from D1 in view of the common general knowledge.

It is not disputed by the opponent that, like D12, D1 does not disclose selection means for switching from controlling transmembrane pressure to controlling replacement fluid flow rate when the replacement fluid flow rate threshold is exceeded and switching from controlling replacement fluid flow rate to controlling transmembrane pressure when the transmembrane pressure threshold is exceeded.

As explained above, this distinguishing feature solves the objective technical problem of minimising the

length of the hemodiafiltration or hemofiltration treatment while ensuring the required safety of the patient.

It is accepted that the skilled person knows that the transmembrane pressure and the fluid flow rate are important parameters for dialysis treatment and would consider controlling them in the device of D1. However, as explained above, D1 is not concerned with the objective technical problem solved by the specific selection means claimed. The common general knowledge of the parameters as such cannot prompt the skilled person to implement those means in the apparatus of D1 either, since no link between those means and the problem is taught. In conclusion, the subject-matter of the claim is not obvious starting from D1 in view of the common general knowledge.

- 6.3 Hence, the subject-matter of the claim is inventive (Article 56 EPC).
7. As explained, the opponent's objections based on D12 are no bar to the patentability of the subject-matter of the claim, and in the Board's view the same applies to D9 to D11. It follows that it is not necessary for the Board to establish whether D9 to D12 were publicly available at the valid priority date of the patent or to hear Mr Dreyhsig as a witness.
8. Since the opponent's objections fail and the Board has no others, the patent may be maintained on the basis of the only claim of the request held allowable by the Opposition Division in the impugned decision.

Order

For these reasons it is decided that:

The appeal of the opponent is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated