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D E C I S I O N
of 7 June 1994

Case Number: T 0160/93 - 3.2.2

Application Number: 86830312.4

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IPC: A61M 1/34

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Title of invention:
Blood-purifying apparatus

Patentee:
Bellco S.p.A.

Opponent:
Fresenius AG

Headword:
-

Relevant legal norms:
EPC Art. 56

Keyword:
"Inventive step (no)"

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Case Number: T 0160/93 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 7 June 1994

Appellant: (Opponent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office dated 10 December 1994 rejecting the opposition filed against European patent No. 0 222 709 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: H. Seidenschwarz
Members: M. Noël
J. Van Moer

Summary of Facts and Submissions

I. European patent No. 0 222 709 was granted on the basis of European patent application No. 86 830 312.4. Independent Claim 1 reads as follows:

"Apparatus for the purifying of blood using the process of haemofiltration or of combined haemodialysis-haemofiltration, wherein the required balance between the liquid (3) removed from the blood (ultrafiltrate) and the replacement liquid (33) is achieved by regulation of the flow of the liquids with the use of first (7) and second (8) volumetric pumps for the ultrafiltrate and the replacement liquid, respectively, whose speeds of operation are regulated, **characterised** in that means (5,40,42,9) are provided for positively controlling, in real time, the amount of air present in the liquid circuit, wherein first means are provided for controlling, in real time, the amount of air present in the ultrafiltrate and are arranged to separate the air from the liquid body of the ultrafiltrate itself, second means (5) are provided for detecting the reduction in the liquid body due to the increase of the gaseous part, for deactivating the first volumetric pump (7) for the ultrafiltrate, and for activating a suction pump (9) for removing the excess gases, and finally third means (4) are provided for detecting when the liquid body reaches the normal quantity and for stopping the suction pump (9) as a consequence, at the same time restarting the first volumetric pump (7) for the ultrafiltrate."

II. The opposition was rejected by the Opposition Division for the reasons that the claimed subject-matter was

novel and implied an inventive step, having regard in particular to the prior art documents:

(1) "Kinetics of Hemodiafiltration II" by Henderson *et al*, J. Lab. Clin. Med., 85 (1975), pp. 373 and 374
(5) DE-A-2 901 628
(6) EP-A-0 044 694
(7) DE-C-2 544 258
(8) DE-A-2 838 414.

III. The Opponent lodged an appeal against this decision. A Statement of Grounds was filed and the appropriate fee was paid in due time.

IV. At the oral proceedings the Appellant argued substantially that the subject-matter of Claim 1 did not involve an inventive step with respect to the combination of the teaching of document (1), which disclosed a blood purifying apparatus for performing the combined process of haemodiafiltration, with the teaching of either documents (5), (7) or (8).

V. The Respondent (Proprietor of the patent) submitted that it was quite immaterial whether document (5) or document (6) was regarded as the starting point. What was significant for deciding on the presence of an inventive step was the simultaneous consideration of all features recited in Claim 1 taken as a whole.

In the haemofiltration apparatus according to document (5), de-aerating of the ultrafiltrate circuit was not dealt with. Extraction of the ultrafiltrate from the filter was not caused by the volumetric pump P1, but rather by the depression created by the air pump PU

which continuously controlled the ultrafiltrate. Therefore, this pump was to be considered as dominating the haemofiltration process.

Documents (7) and (8) referred to haemodialysis processes and associated apparatus in which no replacement liquid was provided. In particular, document (7) described a de-aerating arrangement located in the dialysis solution circuit, whereby the same pump was used for removing the air present in the dialysis solution and the ultrafiltrate flowing from the dialysator, successively. Although the general concept of degassing a liquid circuit was known per se from these documents, the system for controlling the air present in the liquid circuit was quite different from the control system provided in the present patent; therefore, even by combining the teachings of documents (5) and (7) or of documents (5) and (8) the skilled person would not have arrived at the subject-matter of Claim 1.

VI. The Appellant requests that the decision under appeal be set aside and that the European patent be revoked.

The Respondent requests that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. *Closest prior art*

2.1 Document (6) describes an apparatus for plasma separation or exchange by a double filtration process using two filters. The first filter 5 performs the separation into a plasma fraction and a corpuscular fraction, whereas the second filter 11 separates the plasma fraction into a high molecular weight fraction to be removed from the circuit and a low molecular weight fraction to be returned to the patient together with the corpuscular fraction. To supplement the plasma removed in the second filter, a replacement liquid is taken from a reservoir 16 and added to the low molecular weight fraction. The flow rates are adjusted through associated control pumps M4 and M3 so that the amount of the high molecular weight fraction which is withdrawn and the amount of the replacement liquid are equal.

In the embodiment according to document (6), only the second filter 11 is provided with a membrane 10 having ultrafiltration capacities. For that reason, it is comparable with the filter 1 used in the apparatus according to the patent in suit. However, in document (6), there is no provision of an ultrafiltrate reservoir between second filter 11 and pump M3, so that the control of air possibly present in the liquid circuit by detecting the liquid level in the reservoir is neither contemplated nor possible. On the basis of these structural as well as functional differences, the

apparatus as disclosed by document (6) is not regarded as the closest prior art.

2.2 Document (5) represents the closest prior art document. It describes an apparatus for purifying blood using the process of haemofiltration wherein the required balance between the amount of liquid QF removed and the amount of liquid QS replaced is achieved by regulation of the liquid flow rates with the use of volumetric pumps P1 to P3. The pump P1 is responsible in conjunction with pump P3 for the ratio of the portion QF-QAbn of ultrafiltrate which is dispensed with (to be replaced by substitution fluid pumped through the pump P2) to the portion QAbn of ultrafiltrate which is sent to the measuring container MB to define the weight reduction of the patient.

As mentioned in document (5) (cf. page 2, second paragraph), the speeds of the motors M2 and M3 for driving the pumps P1 and P3 respectively, are controlled in response to the detection, by measuring means MZ, of the level of the ultrafiltrate in a reservoir AB, whereby both motors M2 and M3 are stopped whenever a minimum liquid level is reached. Since it is not specified in the preamble of the Claim 1 in suit that the speeds of the volumetric pumps for the ultrafiltrate and for the replacement liquid should be regulated separately, it is of no consequence whether both pumps P1 and P2 are linked mechanically to the same motor M2 and possibly driven at the same speed.

2.3 Moreover, in the apparatus according to document (5), air is withdrawn from the reservoir AB through a suction pump PU driven by a motor M1. Although it is

specified in the description that the purpose of the suction pump is to create a vacuum for draining the filtrate from the filter HF, it is clear that de-aerating of the liquid circuit is achieved simultaneously, since the arrangement corresponds to that used in the contested patent (cf. reservoir 3 and air pump 9). Similar means arranged in the same way and operated under the same conditions do normally produce the same technical effects.

In this respect, the Respondent argued that, in document (5), the ultrafiltration process was essentially controlled by the air pump PU whereas in the patent it was the low pressure created by the volumetric pump 7 which caused the ultrafiltrate to flow (cf. column 3, lines 56 to column 4, line 3). However, it is also mentioned (cf. column 5, lines 17 to 20) in the patent in suit that the ultrafiltrate accumulates in the reservoir as a result of the suction pump 9. It is therefore the combined suction effects of both the ultrafiltrate and the air pumps which cause extraction of the filtrate from the filter. In the same way, removal of air possibly present in the liquid circuit is also obtained by the arrangement of document (5).

3. *Problem and solution*

In whatever way the arrangement according to document (5) actually operates, the control of the amount of air present in the liquid circuit is neither specifically mentioned nor sought. With respect to this prior art, the problem underlying the present patent was, therefore, to provide means for controlling and

possibly reducing the air accidentally present in the liquid circuit so as to restore normal operation of the apparatus, with the view to controlling the exact quantity of ultrafiltrate to be replaced (cf. column 4, lines 52 to 57 and column 6, lines 9 to 12).

The solution to this problem is given by the characterising features of Claim 1 which are distinguished over the closest prior art document, i.e. by means for controlling in real time the amount of air in the ultrafiltrate, namely:

- means (sensor 5) for detecting the reduction in the liquid body due to the increase of the gaseous part, for deactivating the volumetric pump 7 for the ultrafiltrate and for activating the suction pump 9 for removing the excess gases; and

- means (sensor 4) for detecting when the liquid body reaches the normal quantity and for stopping the suction pump 9 as a consequence, at the same time restarting the volumetric pump 7 for the ultrafiltrate.

The liquid level outputs from the sensors 4 and 5 actuate simultaneously and inversely both the air pump 9 and the ultrafiltrate pump 7 (i.e. one is opened whenever the other is closed), so that the above-mentioned features are not only of the same nature but also symmetrical in their function; thus, they can be reduced to one and the same technical feature for the assessment of inventive step.

4. *Novelty*

In none of the documents revealed in the proceedings are all the features of Claim 1 mentioned in combination. Therefore, its subject-matter is regarded as novel over the prior art. Besides, novelty was not questioned by the parties.

5. *Inventive step*

5.1 Faced with the problem of controlling the undesirable presence of air in a liquid circuit, the skilled person will necessarily turn to document (7) which refers to the same technical field and proposes means for degassing a dialysis solution in a haemodialysis apparatus.

As mentioned in the patent (column 1) haemodialysis and haemofiltration are two neighbouring blood-purifying processes, according to which impurities or toxic substances are removed from blood through a porous membrane in the filter. The main difference is that in haemodialysis, impurities of low molecular weight pass by diffusion through a membrane having small-sized pores whereas, in haemofiltration, impurities of high molecular weight are removed together with the plasma (ultrafiltrate) by convection through a membrane having pores of larger size.

However, in both processes the quantity of liquid removed (used dialysis solution in haemodialysis; ultrafiltrate in haemofiltration), is to be controlled to determine the accurate quantity of liquid taken from the patient through the filter. Exact determination of the removed quantity of liquid requires that air accidentally present in the circuit be extracted.

Therefore, the problem of de-aerating a liquid circuit is addressed in the same way for the apparatus described in document (7) (cf. from column 2, line 68 to column 3, line 24) as for the apparatus according to the present patent (cf. column 4, lines 52 to 57 and column 6, lines 9 to 12).

5.2 Document (7) describes with reference to figures 1 to 3 a haemodialysis apparatus comprising a reservoir 8 located on the return circuit of the dialysis solution, downstream of the dialyser 4, and connected with an outlet tube 12 and a pump 9. The outlet tube is paralleled by a conduit 14 connected with a control valve 15. Two level sensors 16,17 are provided on the reservoir for appropriately operating/stopping the pump and the valve means in response to the detection of the liquid level. The sensor outputs are processed in a control device 18 (cf. column 4, lines 40 to 45).

The pump 9 works selectively as a suction pump for removing the air present in the dialysis solution circuit or as a volumetric pump for drawing a predetermined amount of ultrafiltrate (column 4, lines 10 to 21). If, by reason of the presence of air in the liquid circuit the level in the reservoir falls abnormally below the low level sensor 17, the pump acts as an air pump. In order to achieve rapid withdrawal of air trapped in the reservoir, the valve 15 is opened and the pump 9 is operated at a higher speed. When the liquid level increases again up to the high level sensor 16, the valve is closed and the pump acts as a pump of ultrafiltrate, at a reduced speed (cf. column 4, lines 46 to 62).

In document (7), de-aerating and ultrafiltrate circuits actually merge into one another, so that only one pump is necessary, whereas in the patent the two circuits are separated and each provided with one pump. However, both arrangements are functionally equivalent, when considering that only one pump is operated at one and the same time in the patent embodiment, i.e. when the air pump 9 works, the pump 7 of ultrafiltrate is stopped, and vice versa, whereas in document (7), since only one fluid can be drawn at a time, air pumping automatically excludes liquid extraction and vice versa. Moreover, the pump operates as an air pump only in response to low level detection, as is the case in the present patent.

5.3 Since the principle solution of removing the air present in a liquid circuit by means of a suction pump controlled by two level sensors located on the liquid reservoir was known from the arrangement of document (7), the skilled person was inevitably led, on the basis of normal design practice in control systems, also to subject the functioning of the air pump PU used in document (5) to a liquid level sensor. The more so, since the control of said pump PU by a sensor (BLD) is already known from this document, despite the fact that said sensor is not assigned to level detection.

5.4 At the oral proceedings, the Respondent explained that with the arrangement as claimed in the present invention, air removal was performed more safely and more reliably without any risk for the patient since, by using two pumps so arranged that when one is working the other is not, any overpressure on the porous membrane giving rise to the saturation of the same

without a corresponding increase of the amount of ultrafiltrate taken from blood, could be avoided.

The Board does not accept this line of argument because in the embodiment of document (5) also, the ultrafiltrate pump P1 is closed whenever a minimum level of liquid in the reservoir AB is reached (cf. page 3, third paragraph). Therefore, the risk of excessive increase in the pressure gradient on the membrane is also excluded, even if the skilled person had decided to operate the suction pump PU in response to the detection of the minimum level.

5.5 For the foregoing reasons, the subject-matter of Claim 1 lacks any inventive step with respect to the state of the art and therefore does not meet the requirements of Article 56 EPC. As a consequence, the contested patent cannot be maintained.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.

2. The European patent is revoked.

The Registrar: The Chairman:

J. Rückerl H. Seidenschwarz