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Datasheet for the decision of 25 November 2015

Case Number: T 0096/12 - 3.2.02

Application Number: 96919089.1

Publication Number: 0833673

IPC: A61M1/36

Language of the proceedings: EN

Title of invention:
Apparatus for controlling concentrations in vivo and in tubing systems

Patent Proprietor:
Terumo BCT, Inc.

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 87, 100(a), 54, 56, 100(b)

Keyword:
Claims interpretation
Priority - validity of priority date (yes)
Grounds for opposition - insufficiency of disclosure (no)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:
G 0002/98, T 0410/96, T 0240/11, T 0565/12

Catchword:

Europäisches Patentamt
European Patent Office
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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 0096/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 25 November 2015

Appellant: (Patent Proprietor)	Terumo BCT, Inc. 10811 West Collins Avenue Lakewood, CO 80215 (US)
Representative:	Roberts, Mark Peter J A Kemp 14 South Square Gray's Inn London WC1R 5JJ (GB)
Appellant: (Opponent)	Fresenius Medical Care Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg (DE)
Representative:	Herrmann, Uwe Lorenz - Seidler - Gossel Widenmayerstrasse 23 80538 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 16 November 2011 concerning the maintenance of European Patent No. 0833673 in amended form.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	D. Ceccarelli
	C. Körber

Summary of Facts and Submissions

I. The patent proprietor and the opponent have both appealed the Opposition Division's decision, dispatched on 16 November 2011, concerning the maintenance of European patent No. 0 833 673 according to the then pending second auxiliary request.

II. The patent was opposed on the grounds of insufficiency of disclosure (Article 100(b) EPC) and lack of novelty and inventive step (Article 100(a) EPC).

III. In its decision, the Opposition Division held that the priority claim was not valid for the subject-matter of claim 1 of the patent as granted. As a result, the state of the art comprised the following document:

D3: US-A-5,421,812.

Since D3 was novelty-destroying for the subject-matter of claim 1, the patent could not be maintained as granted.

IV. The notice of appeal of the appellant opponent was received on 16 January 2012. The appeal fee was paid the same day. The statement setting out the grounds of appeal was received on 26 March 2012.

The notice of appeal of the appellant proprietor was received on 23 January 2012. The appeal fee was paid the same day. The statement setting out the grounds of appeal was received on 16 March 2012.

V. The appellant proprietor replied to the statement of grounds of the appellant opponent by letter dated 13 August 2012. The appellant opponent replied to the

statement of grounds of the appellant proprietor by letter dated 13 August 2012.

VI. The Board summoned the parties to oral proceedings and set out its provisional opinion in a communication dated 11 September 2015.

VII. The appellant proprietor informed the Board by letter dated 23 October 2015 that it would not be represented at the oral proceedings.

VIII. Oral proceedings took place on 25 November 2015 in the absence of the appellant proprietor.

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

The appellant proprietor had requested in writing that the decision under appeal be set aside and that the patent be maintained as granted or, in the alternative, on the basis of one of the first to fourth auxiliary requests, filed with letter dated 16 March 2012, and the fifth to eighth auxiliary requests filed with letter dated 13 August 2012.

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

D1: U.S. patent application serial No. 08/472,931;
D4: EP-A-0 654 277;
D5: "Adaptive control of anticoagulation during hemodialysis", Jannett T.C. et al., Kidney International, Vol. 45 (1994), pp. 912-915.

X. Claims 1 and 3 of the patent as granted read as follows:

"1. An extracorporeal blood processing apparatus for processing blood from a donor comprising means (12,24) for receiving blood from the donor at an inlet flow rate; means for processing the blood (26); and means (34) for returning at least a fraction of the processed blood to the donor at an infusion rate; **characterized in that** said apparatus comprises:

means (80) for predicting a maximum level of anticoagulant that may be present in the donor;
means (80) for estimating the level of anticoagulant in the donor;
means (80,16) for varying the amount of anticoagulant added to the blood so that the estimated level of anticoagulant in the donor does not exceed the predicted maximum level of anticoagulant in the donor; and
means (80) for varying the infusion rate of the processed blood returned to the donor to maximize the inlet flow rate while simultaneously preventing the estimated level of anticoagulant in the donor from exceeding the predicted maximum level."

"3. The apparatus of claim 1 or 2 wherein the infusion rate varying means further comprise means (80) for determining an optimal infusion rate profile so that the anticoagulant achieves a level in the donor that approaches but remains below the predicted maximum donor anticoagulant level."

Claims 2 and 4 to 13 are further dependent claims.

XI. The arguments of the appellant opponent may be summarised as follows:

a) Construction of functional features

In the claims the extracorporeal blood processing apparatus was defined, inter alia, in terms of "means plus function". The construction of such a way of claiming, as far as the limiting effect on the defined apparatus was concerned, had to be consistent between the assessment of sufficiency of disclosure on the one hand and of novelty and inventive step on the other. It could not be accepted that for assessing novelty and inventive step the claimed "means plus function" had to be interpreted as means carrying out the specified functions autonomously and automatically, while for assessing sufficiency of disclosure they had to be construed as simply implying that the specified functions could somehow be carried out with them. Although according to the current version of the Guidelines for Examination in the European Patent Office, F, IV-4.13, in the data processing field features defined by "means plus function" had to be construed more restrictively than in other technical fields, the practice of the European Patent Office was not clear in this respect. The Guidelines had only recently been modified, the previous version not having differentiated between the data processing field and other technical fields. Moreover, the Guidelines were not binding for the boards of appeal. Even several recent decisions of the first instance had not followed the more restrictive interpretation.

b) Insufficiency of disclosure

The invention as defined in claims 1 and 3 of the patent as granted comprised several functional features which, in view of the information provided in the patent, could not be carried out by the person skilled in the art.

Claim 1 defined "means (80) for predicting a maximum level of anticoagulant that may be present in the donor". According to the disclosure as a whole, however, the blood processing apparatus as claimed did not predict any such maximum level, since the latter was simply stored in a controller of the apparatus. Even assuming that the provision of a value of the maximum level implicitly involved a prediction, it was not disclosed how that prediction could be made by the blood processing apparatus. The maximum level could be determined separately, for example in view of statistics. Moreover, in the patent there was no concrete definition of the level which could be considered as maximum for a given donor, especially in view of the fact that such a level depended on the particular donor, and did not relate to the claimed apparatus as such.

Claim 1 also defined "means (80) for estimating the level of anticoagulant in the donor" and, depending on their estimation, "means (80,16) for varying the amount of anticoagulant added to the blood". In the patent as a whole, however, a method for estimating the level of anticoagulant in the donor was only described in connection with a biodynamic model relating to a single specific anticoagulant, i.e. citrate. Such a biodynamic

model was not applicable for every anticoagulant in general. Hence the invention as claimed was not sufficiently disclosed over its whole scope.

Claim 1 further defined "means (80) for varying the infusion rate of the processed blood returned to the donor to maximise the inlet flow rate while simultaneously preventing the estimated level of anticoagulant in the donor from exceeding the predicted maximum level". If the "means plus function" had to be interpreted as means carrying out the specified functions autonomously and automatically, in order for this claimed feature to be sufficiently disclosed the patent would have had to clearly teach how to control the infusion rate of the processed blood returned to the donor to achieve the respective claimed function. However, the patent as a whole taught only how to control the infusion rate of the anticoagulant added to the blood. From the disclosure of the patent as a whole and the common general knowledge it was not derivable that these two flow rates were identical or univocally dependent on one another. The amount of anticoagulant added to the blood was negligibly small compared with the amount of blood. Hence, the skilled person would not know how to control the infusion rate of the processed blood returned to the donor so as to achieve the respective claimed function. Moreover, since it was not even clear what could be meant by a maximum inlet flow rate, not even the result to be achieved by the variation of the infusion rate of the processed blood returned to the donor was known. Therefore the skilled person would be left in the dark and could not perform the claimed feature, which merely amounted to a description of

a desired result.

Claim 3 defined "means (80) for determining an optimal infusion rate profile so that the anticoagulant achieves a level in the donor that approaches but remains below the predicted maximum donor anticoagulant level". The mentioned infusion rate could only mean the infusion rate of the processed blood returned to the donor, since that was the only infusion rate defined in independent claim 1. However, the patent did not teach how to control the infusion rate of the processed blood returned to the donor. Hence, it was impossible for the skilled person to determine the optimal infusion rate profile according to claim 3. As a result, its subject-matter could not be carried out.

c) *Validity of the priority claim*

The patent claimed priority from D1. However, the appellant proprietor had filed D3 before D1. Since D3 was novelty-destroying for the subject-matter of the patent as granted, disclosing, in particular, means for varying the infusion rate of the processed blood returned to the donor to maximise the inlet flow rate as defined in claim 1, it constituted the "first application" within the meaning of Article 87 EPC. For this reason alone the priority claim from D1 was not valid.

Moreover, D1 did not disclose an apparatus with means for varying the infusion rate of the processed blood returned to the donor to maximise the inlet flow rate, i.e. the flow rate of the blood entering the blood processing apparatus.

Claims 11 and 12 of D1, on which claim 1 of the patent as granted appeared to be based, defined only one flow rate, i.e. the flow rate of the processed blood returned to the donor. The last feature of claim 11 disclosed that this flow rate was varied in order to maximise it. Consequently, claim 1 of the patent as granted and claim 11 of D1 taught to maximise different flow rates. Where the description of D1 mentioned that the inlet flow rate should be maximised, in particular page 16, lines 28 to 31, it did not teach to do it by varying the flow rate of the processed blood returned to the donor, but rather by optimising the anticoagulant flow rate. That was in no relation with the subject-matter of claims 11 and 12. It followed that D1 did not disclose the same invention as that defined in claim 1 of the patent as granted. Hence, the priority claim was not valid for this reason too.

Moreover, the claims of D1 did not provide any basis for the subject-matter of claim 3 of the patent as granted. In the description of D1 there was no mention that an infusion rate profile for the processed blood returned to the donor was calculated. Even where the description of D1 mentioned determining an infusion rate profile of the anticoagulant, that was not in combination with the remaining features of claim 1 of the patent as granted. It followed that the subject-matter of claim 3 of the patent as granted did not enjoy the priority right claimed from D1 either.

d) Novelty and inventive step

Since the priority claim was not valid for the subject-matter of claims 1 and 3 of the patent as granted, D3 belonged to the state of the art and was novelty-destroying for it. If there were any differences between the subject-matter of those claims and D3, they would not involve an inventive step, as these differences would belong to the common general knowledge.

D5 was also novelty-destroying for the subject-matter of claim 1. In particular, it disclosed a mathematical model of the decay of anticoagulant, useful for estimating the level of anticoagulant in a donor's body. It further disclosed a control of the infusion of anticoagulant in order to reach a given level of anticoagulant in the body as fast as possible (first paragraph of section "discussion" on page 914). This given level had to be interpreted as a maximum within the meaning of claim 1, since that level could be changed and simply stored depending of the particular donor.

If not novelty-destroying, D5 would at least deprive the subject-matter of claim 1 of an inventive step. If the Board held that D5 did not disclose means for varying the infusion rate of the processed blood returned to the donor to maximise the inlet flow rate, then the problem to be solved by this feature had to be regarded as obtaining a more efficient blood processing method. D5 itself indicated that the time needed to carry out the method was an important factor. D4 was concerned with the optimisation of a blood

processing method and disclosed that the latter should be carried out in a minimum amount of time (page 3, lines 48 to 53). It also disclosed that the inlet flow rate had to be maximised (page 13, lines 28 and 29). In view of the teaching of D4 the skilled person would arrive at the subject-matter of claim 1 in an obvious way.

The subject-matter of claim 1 of the patent as granted was also not inventive in view of D4 as the closest prior art. D4 failed to disclose a means for estimating the level of anticoagulant in the donor as well as means for varying the amount of anticoagulant added to the blood depending on that estimated level. In D4 the flow rate of the anticoagulant was maintained constant (page 1, lines 35 to 39). The problem to be solved was to tailor the control to best suit a specific donor, so that a higher anticoagulant rate could be possible. D5 taught to estimate and control the anticoagulant flow rate in order to provide a solution to this problem (page 913, section "clinical trials"). The skilled person would therefore combine D4 and D5, thereby arriving at the subject-matter of claim 1 in an obvious way.

XII. The arguments of the appellant proprietor may be summarised as follows:

a) Construction of functional features

When assessing the limiting effect of features defined as "means plus function" the function could not be disregarded. An apparatus defined by functional features would be novel over an apparatus that did not perform the same functions.

It had long be the case at the EPO that a controller for performing certain functions was anticipated only by a prior art controller programmed to perform those same functions and not by a prior art controller programmed to perform different functions but suitable for being reprogrammed to perform the same functions. The "means for" clauses of the claims should be construed accordingly, with due regard being given to their functional features, and consistently for the examination of different articles under the EPC. The fact that the Guidelines for Examination in the European Patent Office had been updated only recently was of no relevance in this respect. The first-instance decisions referred to by the appellant opponent allegedly showing an "inconsistent practice" were of no relevance either, since they related to different claim features in a different context before a different instance of the EPO with different parties.

b) *Insufficiency of disclosure*

The claimed invention was disclosed sufficiently clearly and completely in the patent as granted for it to be carried out by the person skilled in the art.

The claimed means for predicting a maximum level of anticoagulant that may be present in the donor, when properly interpreted in the light of the disclosure as a whole, encompassed the simple use of a generic "maximum level" for a particular donor. Such a use was disclosed on page 6, lines 9 to 11 of the patent. The claimed means for predicting comprised elements of a controller and

a memory used to store a value corresponding to that generic "maximum level", which could be derived from published general results. The "prediction" could be no more than the stored value. It was nevertheless a "prediction", since the value was based on past experience, not a measurement. Moreover, paragraph [0060] of the patent explained the possibility of a medical careworker modifying the stored value depending on how the donor reacted to a previous treatment. That was another, donor-specific, "prediction" of a "maximum level" by the means for predicting according to the disclosure of the patent. Based on these two examples the skilled person would be able to work across the practical breadth of the claims as interpreted in the light of the description.

The claimed means for estimating the level of anticoagulant in the donor and the means for varying the amount of anticoagulant added to the blood depending on the estimation had not only been disclosed for citrate as an anticoagulant, but also for heparin and other anticoagulants having a predictable decay rate (paragraph [0062] of the patent). The decay profile of heparin in the human body was well known. Citrate and heparin were the most common anticoagulants used in blood processing. Based on the disclosure concerning them, the skilled person would be able to carry out those means over their whole practical scope.

The feature of the means for varying the infusion rate of the processed blood returned to the donor to maximise the inlet flow rate while simultaneously preventing the estimated level of

anticoagulant in the donor from exceeding the predicted maximum level described how the apparatus was controlled. Figures 1 and 3 disclosed that it was possible to control the various flows in the apparatus in order to achieve the claimed function. Specific equations for providing an anticoagulant infusion rate profile in order to maximise the inlet flow rate while simultaneously preventing the estimated level of anticoagulant in the donor from exceeding the predicted maximum level were disclosed in the description, in particular at paragraphs [0038] to [0055]. Varying the infusion rate of anticoagulant into the donor had an effect on the rate of the processed blood returned to the donor, which was readily derivable by the person skilled in the art. As far as the maximisation of the inlet flow rate was concerned, the description explained how the flow rate of blood that could be supported in the tubing was related to the amount of anticoagulant in the tubing, and that the amount of anticoagulant in the donor was related to the amount of anticoagulant in the blood. Based on these explanations the skilled person would have no problem practising the invention, as claimed, in a practical sense.

An optimal infusion rate profile within the meaning of the patent was a technically feasible profile for which it would not be possible at any time to increase the amount of anticoagulant, and thereby increase the inlet flow rate, without in the future exceeding the maximum level of anticoagulant in the donor. Paragraph [0052] of the patent explained that the desired optimum profile could be that of a critically dampened

first order function.

c) *Validity of the priority claim*

In order to assess whether a claimed invention is the "same invention" as disclosed in a previous document, the same criteria as the assessment of compliance with Article 123(2) EPC should be applied.

D3 did not disclose a blood processing apparatus comprising means for varying the infusion rate of processed blood returned to a donor to maximise the inlet flow rate, as required by claim 1 of the patent as granted. D3 was concerned with modelling the amount of anticoagulant in the circuit of a blood processing apparatus or in a donor to ensure that a safe level was not exceeded. That permitted "large flow rates" but fell short of maximised flow rates as defined in claim 1 of the patent as granted. It followed that D3 could not constitute the "first application" within the meaning of Article 87 EPC.

D1 provided a basis for the subject-matter of claim 1 of the patent as granted. In particular, claims 11 and 12 read in conjunction with several passages of the description provided a basis for the claimed means for varying the infusion rate of processed blood returned to a donor to maximise the inlet flow rate. D1, in particular page 6, lines 19 to 23 and 29 to 34, page 8, lines 8 to 22 and page 19, lines 6 to 8, also provided a basis for the means for determining an optimal infusion rate profile, as defined in claim 3 of the patent as granted.

It followed that the priority claim from D1 was valid for claims 1 and 3 of the patent as granted. As a consequence, D3 did not belong to the state of the art for the subject-matter of those claims.

d) Novelty and inventive step

D5 was not novelty-destroying for the subject-matter of claim 1 of the patent as granted. In particular, it failed to disclose means for predicting a maximum level of anticoagulant that might be present in the donor and varying the amount of anticoagulant added to the blood so that the anticoagulant in the donor does not exceed the predicted maximum level. Moreover, D5 taught nothing about maximising the inlet flow rate. On the contrary, the blood flow rate entering the apparatus of D5 was kept constant throughout the whole blood processing procedure.

For the analysis of inventive step starting from D5 as the closest prior art, the problem to be solved was to make the blood processing procedure more time-efficient. No document of the available prior art taught that the solution to this problem would be to change the inlet flow rate to maximise it. It followed that, starting from D5, the skilled person would not arrive at the subject-matter of claim 1 in an obvious way.

D4 disclosed to set a maximum specific infusion rate of anticoagulant and keep it constant during the whole blood processing procedure. It failed to disclose all the means defined in claim 1 of the

patent as granted. Starting from D4 as the closest prior art, the problem to be solved was to make the procedure more time-efficient while maintaining donor safety. D5 did not disclose changing the inlet flow rate of the blood. It followed that the combination of D4 with D5 did not render obvious the subject-matter of claim 1.

Reasons for the Decision

1. The appeals are admissible.

2. Although having been duly summoned by communication dated 11 September 2015, the appellant proprietor was not present at the oral proceedings as announced by letter dated 23 October 2015. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued without this party.

3. The invention

The invention as defined in claim 1 of the patent as granted relates to an extracorporeal blood processing apparatus, for example of the kind used to perform apheresis procedures, in order to collect certain blood components from a donor.

In such procedures, blood is drawn from a donor at an inlet flow rate, processed in the apparatus in order to collect the desired components such as platelets, red blood cells or plasma, and then partly re-infused, i.e. mostly the components left, into the donor.

The greater the inlet flow rate, the faster the procedure will be to collect a given amount of desired

components. However, there are limitations on that flow rate, for example due to the need of having anticoagulant in the tubing set of the blood processing apparatus, in order to permit blood processing and to prevent haemostasis. In general, the higher the flow rate of anticoagulant added into the blood tubing set, the higher the inlet flow rate can be (paragraph [0003] of the patent).

However, the anticoagulant added into the blood tubing set will be infused into the donor, who needs time to metabolise it thereby removing it from his circulatory system. Since the donor can tolerate only a certain amount of anticoagulant in his circulatory system without developing adverse physiological reactions, the flow rate of anticoagulant which can be added into the blood tubing set is limited, which poses a limitation on the inlet flow rate and, by consequence, on the speed of the procedure (paragraph [0004] of the patent).

The claimed invention aims to maximise the inlet flow rate while maintaining the amount of the anticoagulant in the donor under a maximum level.

In order to do so, it proposes an extracorporeal blood processing apparatus with means for estimating the level of anticoagulant in the donor, for example with a prediction model which takes into account the flow rate of anticoagulant drawn from and infused into the donor, as well as the amount of anticoagulant metabolically cleared from the donor's body.

4. Construction of functional features

Claims 1 and 3 in particular are mainly drafted in terms of functional features, also called "means plus function". Such features are to be construed in the context of the data-processing/computer program field, as they are employed to define a controller (80 in figure 1) of the claimed blood processing apparatus.

The Board agrees with the appellant opponent that the limiting effect assigned to such features should be consistent when dealing with different requirements of the EPC.

In the Board's view, on a proper construction the claimed apparatus should be interpreted as adapted to carry out the specified functions. In the present instance, this implies that the controller of the blood processing apparatus, as programmed, is adapted to do so. An unprogrammed, or differently programmed, controller, as is, would simply be unsuitable for carrying out those functions.

Such a construction is in line with the established jurisprudence of the boards of appeal (for example, T 410/96, point 6 of the reasons, and more recently, T 240/11 and T 565/12).

The passage in the Guidelines for Examination in the European Patent Office, F, IV-4.13 is also consistent with this construction. The Guidelines, while not authoritative on the boards of appeal, aim to ensure a uniform practice of the departments of first instance of the European Patent Office. The fact that, as the appellant opponent argued, some decisions of those departments may deviate from the Guidelines is

completely irrelevant for the present case.

In summary, a generic controller does not fall, as such, under the definition of the means defined in claims 1 and 3. A controller specifically programmed to perform the claimed functions does.

5. Insufficiency of disclosure

In the Board's view, in the assessment whether the claimed invention is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, the description and the drawings create the context and cast a light on the meaning of the terms employed in the claims. Hence, they must be duly considered first of all when establishing the extent of the claimed subject-matter. Any exercise based on an interpretation of the claims out of context, aiming to show that that very interpretation was not sufficiently disclosed, is clearly inappropriate.

5.1 As regards the disclosure of the means for predicting a maximum level of anticoagulant that may be present in the donor as defined in claim 1 of the patent as granted, the Board considers paragraphs [0037] and [0060], as pointed out by the appellant proprietor, to be the most relevant.

In the light of these paragraphs, a prediction of a maximum level of anticoagulant within the meaning of the claim has to be interpreted as making available a certain value of the anticoagulant level (MADEC for citrate), stored in a controller (80 in figure 1), for a subsequent calculation model. This value is not to be exceeded by the level of anticoagulant in the donor

estimated according to that calculation model applied to the blood processing procedure. In paragraph [0037] it is clearly explained that the maximum could be the highest value for which a majority of donors of a given class are not expected to suffer adverse side effects, as empirically determined. Paragraph [0060] discloses that such a value could be customised for a specific donor, based on previous blood processing procedures with the specific donor. This empirical determination of the maximum, explained for citrate as anticoagulant, is generally applicable to other anticoagulants. The fact that the maximum level may be donor-specific, as the appellant opponent argued, is irrelevant, since the concept of maximum within the meaning of the claim relates to the value to be implemented in the calculation model, which is intrinsic to the claimed apparatus.

5.2 The means for estimating the level of anticoagulant in the donor and the means for varying the amount of anticoagulant added to the blood depending on the estimation as defined in claim 1 of the patent as granted are disclosed in detail for citrate, based on the biodynamic model described in paragraphs [0040] to [0046] in conjunction with figure 2. Paragraph [0034] explicitly teaches that this disclosure could be extended to "heparin, or any coagulant having a known decay rate in the body or decay profile that can be described by a biodynamic model".

In the Board's view, this disclosure enables to skilled person to carry out those means over their technically meaningful scope. The argument of the appellant opponent that anticoagulants may exist for which a biodynamic model is not available is not convincing. The invention does not aim to protect the

anticoagulants as such, but relates to an apparatus employing, in use, a certain anticoagulant. The anticoagulant must satisfy the conditions for a suitable employment within the constrictions of the claimed apparatus. Hypothetical unpredictable anticoagulants, assuming that they exist, would simply not be contemplated by the person skilled in the art wishing to implement the invention.

5.3 As regards the means for varying the infusion rate of the processed blood returned to the donor to maximise the inlet flow rate while simultaneously preventing the estimated level of anticoagulant in the donor from exceeding the predicted maximum level according to claim 1 of the patent as granted, the patent explains in paragraph [0049], dealing with citrate as the anticoagulant, that a mathematical transfer function is used to develop an explicit equation for the anticoagulant infusion rate (I) to the donor per liter of its total blood volume (TVB). It is stated that:

> "*This equation for I represents the optimum time profile for the anticoagulant infusion rate [...] where it is desired that the donor/patient citrate concentration approach [...the maximum allowable donor estimated concentration] as rapidly as practical constraints on [...the instant flow rate of the anticoagulated blood in the inlet line of the blood processing apparatus] will allow and, thereby maximize the total volume of blood processed during the procedure.*"

The mathematical transfer function used is a critically damped first order function, which is illustrated in paragraphs [0052] to [0057] together with equations depending on it.

This amounts to a disclosure of a means for maximising the anticoagulant infusion rate (Q_{ac} in figure 2, i.e. what is pumped by pump 16 in figure 1), depending on the procedure time.

In this context, and in view of the disclosure as a whole, the Board is of the opinion that the maximisation of the inlet flow rate as defined in the claim cannot be interpreted as reaching an absolute maximum in a mathematical sense, but rather as reaching a varying maximum, increasing with time during the procedure. Such a varying maximum depends also on practical physical and mechanical constraints known by the skilled person, e.g. the operational limits of the pumps and the centrifuge of the blood processing apparatus and the maximum flow rate of blood which can be safely drawn and infused back into the donor.

The maximum possible flow rate of the whole blood extracted from the donor (Q_{wb} in figure 2), which is specific to the particular blood processing apparatus such that hemostasis is prevented and blood processing is permitted (paragraph [0003] of the patent), depends on the maximum anticoagulant infusion rate. In order to establish the precise dependence, the skilled person only has to know the specific blood processing apparatus or, in the alternative, has to perform some trial and error.

According to the patent, in particular figure 2, the flow rate of the anticoagulated blood in the apparatus (Q_{in}) is the sum of the anticoagulant infusion rate (Q_{ac}) and the flow rate of the whole blood extracted from the donor (Q_{wb}). The corresponding flow rate of the

processed blood returned to the donor (Q_{ret}) is given by the difference between the flow rate of the anticoagulated blood in the apparatus (Q_{in}) and the flow rates of the collected blood components (Q_c), established by pumps 28 and 29 taking into account any replacement fluid pumped by pump 40 (figure 1).

It follows that, contrary to the submissions of the appellant opponent, the patent discloses not only how the infusion rate of the anticoagulant added to the blood should be controlled in order to maximise the inlet flow rate, but also a direct dependence between the anticoagulant flow rate and a corresponding flow rate of the processed blood returned to the donor, as defined in claim 1.

Based on this dependency, the skilled person can carry out the claimed means for varying the infusion rate of the processed blood returned to the donor to maximise the inlet flow rate while simultaneously preventing the estimated level of anticoagulant in the donor from exceeding the predicted maximum level without an undue burden.

5.4 As regards the means for determining an optimal infusion rate profile so that the anticoagulant achieves a level in the donor that approaches but remains below the predicted maximum donor anticoagulant level as defined in claim 3 of the patent as granted, they are also sufficiently disclosed in paragraphs [0049] and [0052] to [0057]. According to the patent, the equation for the anticoagulant infusion rate developed from the mathematical transfer function as disclosed in those paragraphs represents an optimum time profile for the anticoagulant infusion rate, and thus, indirectly, for the flow rate of the processed

blood returned to the donor as explained in point 5.3 above.

5.5 It follows that the subject-matter of claims 1 and 3 of the patent as granted is sufficiently disclosed for it to be carried out by a person skilled in the art. As a result, the ground for opposition under Article 100(b) EPC as raised by the appellant opponent does not prejudice the maintenance of the patent as granted.

6. Validity of the priority claim

As pointed out by the appellant proprietor, in order to assess whether a claimed invention is the "same invention" as in a previous document the same criteria as the assessment of compliance with Article 123(2) EPC should be applied. More particularly, a document can only be considered as disclosing the "same invention" as defined in a claim if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from that document as a whole (opinion G2/98, order).

6.1 Claim 1 of the patent as granted requires that the extracorporeal blood processing apparatus comprises "means for varying the infusion rate of the processed blood returned to the donor to maximise the inlet flow rate while simultaneously preventing the estimated level of anticoagulant in the donor from exceeding the predicted maximum value".

D3, which discloses an extracorporeal blood processing apparatus of the same kind as in the patent, is mainly concerned with maintaining a desired anticoagulant level in the apparatus and the donor (column 2, lines

56 to 60). In column 6, lines 29 to 39, D3 further discloses that it is desirable that the "anticoagulant level in the centrifuge [of the apparatus] be kept at a high level to permit large flow rates, but not so high that the anticoagulant levels in the return line or in the donor/patient become uncomfortably high". The technical considerations behind this control may be somehow similar to those leading to the control of the invention as defined in claim 1. However, as argued by the appellant proprietor, D3 does simply not teach to maximise the inlet flow rate, but rather focuses on maintaining a high anticoagulant level in the apparatus.

It is noted that, according to the patent, maximising the inlet flow rate results in a variable level of anticoagulant in the apparatus during the procedure (paragraph [0058]), since at the beginning the donor tolerates a higher infusion rate of anticoagulant than at the end. This is even in contrast with the teaching of D3.

It follows that the skilled person cannot derive the subject-matter of claim 1 directly and unambiguously, using common general knowledge, from D3 as a whole.

Hence, D3 cannot be the "first application" within the meaning of Article 87 EPC for the subject-matter of either claims 1 or 3, the latter depending on the former.

6.2 As far as D1 is concerned, the subject-matter of claim 1 of the patent as granted is directly and unambiguously derivable from claim 11 of D1 in view of the disclosure as a whole.

The argument of the appellant opponent that, according to claim 11, it was the flow rate of the processed blood returned to the donor which was maximised, is not convincing. While, literally, one may argue that only one flow rate, i.e. the flow rate of the processed blood returned to the donor, is explicitly defined in claim 11, the Board is of the opinion that, from a technical point of view, the interpretation of the appellant opponent makes little sense. The skilled person would read claim 11 with a mind willing to understand, and in the light of the disclosure of D1 as a whole. The passage on page 6, lines 6 to 9 explains that a significant aspect of the invention disclosed in D1 is to maximise the volume of blood processed during an apheresis procedure. For a procedure lasting a given time, this necessarily requires maximising the inlet flow rate, since the latter is the source of the processed blood. Moreover, the passages on page 6, lines 14 to 23 and 29 to 34, and page 16, lines 28 to 31 expressly teach that the inlet flow rate should be increased/optimised/maximised.

It follows that D1 provides a basis for the invention as defined in claim 1 of the patent as granted.

As the appellant proprietor convincingly argued, D1, in particular page 6, lines 29 to 34 and page 8, lines 8 to 22, which expressly mention optimising the inlet flow rate, also provides a basis for the means for determining an optimal infusion rate profile as defined in claim 3 of the patent as granted.

It is therefore concluded that the priority from D1 is validly claimed for the subject-matter of claims 1 and 3 of the patent as granted.

7. Novelty and inventive step

7.1 Since the priority from D1 is validly claimed for the subject-matter of claims 1 and 3, D3, which was not published earlier than the relevant date, is not prior art for the subject-matter of those claims.

7.2 D5 is concerned with providing a target level of anticoagulation during haemodialysis by means of a computer-controlled system. The haemodialysis system concerned, which constitutes an extracorporeal blood processing apparatus, implicitly comprises means for receiving blood from a donor, means for adding anticoagulant to the blood, means for processing the blood and means for returning at least a fraction of the processed blood to the donor at an infusion rate.

D5 also discloses means for estimating the level of anticoagulant in the donor and means for varying the amount of anticoagulant added to the blood (the ACT measurements and the infusion rate adjustment in the adaptive control mentioned in the section "Clinical trials" on page 913).

The Board also shares the view of the appellant opponent that the target level of anticoagulation specified in D5 (page 912, third paragraph), or even this target level plus the exceeding amount actually permitted by the control (highest point of upper dotted line in figure 1), could be considered the predicted "maximum level of anticoagulant that may be present in the donor" within the meaning of claim 1 of the patent as granted.

It remains the case, however, that D5 does not disclose means for varying the infusion rate of the processed

blood returned to the donor to maximise the inlet flow rate while simultaneously preventing the estimated level of anticoagulant in the donor from exceeding the predicted maximum value. In fact, as the appellant proprietor submitted, D5 does not even teach that the inlet flow rate could be varied during the procedure. With the claimed means, instead, a variation of the infusion rate of the processed blood returned to the donor *to* maximise the inlet flow rate clearly implies a variation of the latter, within the meaning of the patent as a whole.

It follows that the subject-matter of claim 1 is novel over D5.

7.3 As regards the assessment of inventive step, the appellant opponent developed essentially two lines of argument, one based on D5 and the other based on D4 as the closest prior art.

Like the claimed invention, D4 is concerned with a blood component collection system with optimisation capabilities. As disclosed, for example, on page 5, lines 37 to 54 in conjunction with figure 2, the system comprises means for receiving blood from a donor, means for adding anticoagulant to the blood, means for processing the blood and means for returning at least a fraction of the processed blood to the donor at an infusion rate. The system aims to provide for the collection of a maximum quantity of the blood component in a fixed amount of time (page 3, lines 46 to 53). In order to do so, it proposes a prediction model for foreseeing a yield of the blood component before a collection procedure. The model may involve a maximisation of the inlet flow rate based upon a specified infusion rate of anticoagulant, representing

the maximum for an associated donor (page 13, lines 28 and 29, and 35 to 39). As also submitted by the appellant proprietor and not contested by the appellant opponent, with the system of D4 the inlet flow rate is not varied during the procedure. Consequently, as explained under point 7.2 above, D4 fails to disclose means for varying the infusion rate of the processed blood returned to the donor to maximise the inlet flow rate while simultaneously preventing the estimated level of anticoagulant in the donor from exceeding the predicted maximum value within the meaning of claim 1.

Following either line of argument of the appellant opponent, it is noted that neither D5 nor D4 disclose a system comprising means for varying the infusion rate of the processed blood returned to the donor to maximise the inlet flow rate while simultaneously preventing the estimated level of anticoagulant in the donor from exceeding the predicted maximum value.

This feature has the effect of minimising the time of the blood processing procedure necessary to treat a certain amount of blood.

Starting from either document as the closest prior art, the problem to be solved is therefore regarded as how to increase the efficiency of a blood processing procedure.

Since the differentiating feature is not disclosed in the cited prior art, the Board does not see how a skilled person could implement it in the systems of either D4 or D5 in an obvious way.

It follows that the subject-matter of claim 1 and, a fortiori, of its dependent claim 3 is inventive over

the cited prior art.

7.4 As a result, the ground for opposition under Article 100(a) EPC as raised by the appellant opponent does not prejudice the maintenance of the patent as granted.

8. It follows that none of the ground for opposition invoked by the appellant opponent prejudices the maintenance of the patent as granted (Article 101(2) EPC).

9. Under the circumstances there is no need for the Board to consider the auxiliary requests of the appellant proprietor.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained as granted.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated