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**Datasheet for the decision
of 9 November 2007**

Case Number: T 0840/05 - 3.2.02

Application Number: 99203026.2

Publication Number: 0968731

IPC: A61M 1/36

Language of the proceedings: EN

Title of invention:

Method of separating a blood component from whole blood

Applicant:

Baxter International Inc.

Opponent:

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Headword:

-

Relevant legal provisions:

EPC Art. 76(1)

Keyword:

"Extended subject-matter - (no, after amendments)"
"Sequence of divisional applications"

Decisions cited:

G 0001/06

Catchword:

-



Case Number: T 0840/05 - 3.2.02

DECISION
of the Technical Board of Appeal 3.2.02
of 9 November 2007

Appellant: Baxter International Inc.
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Deerfield
IL 60015 (US)

Representative: Eric Potter Clarkson LLP
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 8 February 2005
refusing European application No. 99203026.2
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: M. Noël
M. Vogel

Summary of Facts and Submissions

- I. European divisional application No. 99 203 026.2 was refused by decision of the examining division dated 8 February 2005 principally on the basis of Article 76(1) EPC. The present application is a divisional of the earlier application ("parent") No. 95 200 461.2 which is itself a divisional of the more earlier application ("grand parent") No. 91 913 571.5 (published as WO 91/19561).
- II. The appellant (applicant) lodged an appeal against this decision and submitted various sets of amended claims, by notice received on 7 April 2005. The appeal fee was paid on the same day. A statement setting out the grounds of appeal was filed on 17 June 2005.
- III. Oral proceedings were held on 9 November 2007, at the end of which the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request as filed with the notice of appeal, or the first or second auxiliary requests, filed as the second and fourth auxiliary request, respectively, with the notice of appeal, or on the basis of the third auxiliary request filed during the oral proceedings.
- IV. Claim 1 according to the various requests reads as follows:

Main request:

"A method of automatically separating in vitro platelet concentrate or platelet poor plasma from whole

blood, in a blood component separating apparatus (46), comprising:

(a) subjecting whole blood to a separation step to yield the platelet concentrate or platelet poor plasma component; and

(b) adding anticoagulant solution downstream of the separation step so as to provide the platelet concentrate or platelet poor plasma component with anticoagulant in an amount sufficient to prevent clotting."

First auxiliary request:

"A method of automatically separating in vitro platelet concentrate or platelet poor plasma from whole blood, in a blood component separating apparatus (46), comprising:

(a) adding no anticoagulant solution to the whole blood prior to its separation and adding anticoagulant solution after the separation to provide a platelet concentrate or platelet poor plasma component with sufficient anticoagulant to prevent clotting; or

(b) adding anticoagulant solution to the whole blood prior to its separation in an amount that is insufficient to prevent clotting of the blood components created by the separating apparatus and adding further anticoagulant solution after the separation to provide a platelet concentrate or platelet poor plasma component with sufficient anticoagulant to prevent clotting."

Second auxiliary request:

"A method of automatically separating in vitro platelet concentrate or platelet poor plasma from whole blood, in a blood component separating apparatus (46), comprising:

- (a) subjecting whole blood to a separation process to yield a platelet rich plasma component;
- (b) adding anticoagulant solution to the separated platelet rich plasma component in an amount sufficient to prevent clotting; and
- (c) subjecting the platelet rich plasma component to a separation process to yield the platelet concentrate or platelet poor plasma."

Third auxiliary request:

"A method of automatically separating in vitro platelet concentrate from whole blood, in a blood component separating apparatus comprising:

- (a) subjecting whole blood to a separation process to yield a platelet rich plasma component, wherein 4% by volume or less anticoagulant solution is added to the whole blood before separation;
- (b) adding anticoagulant solution to the separated platelet rich plasma component in an amount sufficient to permit adequate storage of the platelet concentrate; and
- (c) subjecting the platelet rich plasma component to a separation process to yield the platelet concentrate."

V. At the oral proceedings the appellant submitted that it resulted from a number of passages as well of the grand parent application as of the parent application that protection was sought for an improved method of obtaining blood components, including platelet concentrate (PC) and platelet poor plasma (PPP), from whole blood. It was also clear that the invention lay in reducing the amount of anticoagulant solution used in comparison to the prior art. As disclosed in the applications, this could be achieved in a number of ways, for example by adding anticoagulant to an isolated component after separation or by reducing or eliminating the amount of anticoagulant added to whole blood before the separation (see in particular page 5, lines 9 to 12 and lines 28 to 34, or page 6, lines 21 to 25 of the grand parent document). Consequently, the different options presented in the various claims 1 according to the main and the auxiliary requests did not contain added subject-matter with respect to the earlier applications as filed.

Reasons for the Decision

1. The appeal is admissible.
2. *Article 76(1) EPC*

According to the order in decision G 1/06 "in the case of a sequence of applications consisting of a root (originating) application followed by divisional applications, each divided from its predecessor, it is a necessary and sufficient condition for a divisional application of that sequence to comply with

Article 76(1), second sentence, EPC that anything disclosed in that divisional application be directly and unambiguously derivable from what is disclosed in each of the preceding applications as filed".

In the present case therefore, where the present divisional application originates from a previous (parent) application which is itself a divisional of an earlier European (grand parent) application, it has to be examined whether the subject-matter of the claims under appeal satisfies the above condition.

3. *Main request*

The subject-matter of claim 1 is not disclosed in the grand parent application as filed, since the claimed method refers to only one separation stage for providing the components PC (platelet concentrate) or PPP (platelet poor plasma), whereas the invention as illustrated and disclosed throughout the grand parent application refers exclusively to a two-stages method of separating a blood component from whole blood by means of two set portions A and B, each comprising a separator 46 and 62, respectively, wherein the components PC and PPP are only obtained after the second separation stage in set B.

The "separation step" referred to in feature (a) of claim 1 of the main request, therefore, has to be seen as being the second separation step which is performed in separator 62 and not in the first separator identified as 46 at the beginning of claim 1. Since adding anticoagulant solution downstream of the second separator 62 was never contemplated in the grand parent

application, feature (b) of claim 1 is neither disclosed nor derivable from this document.

It results that the method defined by the combination of features (a) and (b) is also not disclosed and that the subject-matter of claim 1 of the main request extends beyond the content of the grand parent application as filed, contrary to the requirements of Article 76(1) EPC.

The appellant stated that the method according to claim 1 was supported by the disclosure on page 5, lines 9 to 12 and 28 to 34 of the grand parent application, which refers to the use of a "Haemonetics Model 50 Device". However, the quoted passages are irrelevant because they refer to the state of the art and to a device which performs a one-stage separation process. There is no intermediate stage, and the platelet concentrate is derived directly from the whole blood. Moreover, since the patient is not disconnected during the use of the "Haemonetics Model 50 Device" the separation is not performed in vitro as required by the present claim 1.

Instead, the method presented in the grand parent application uses the "Autopheresis-C Device" which performs a two-stages separation from whole blood, the patient being disconnected after the first separation stage. An anticoagulant solution is added to the PRP obtained after the first separation, in order to produce in vitro, in the next stage, the required PC and PPP components (see page 5, lines 18 to 25; page 8, lines 10 to 24; page 12, line 30 to page 13, line 3 and page 16, lines 17 to 23).

4. *First auxiliary request*

The method defined in claim 1 according to the first auxiliary request comprises two alternatives, separated by the conjunction "or". However, the first alternative identified by (a) in claim 1 under consideration is equivalent to the combination of features identified by (a) and (b) in claim 1 of the main request, since the feature "adding no anticoagulant solution to the whole blood prior to its separation" is equal to "subjecting whole blood (directly and without addition) to a separation step" and "adding anticoagulant solution after the separation" is equal to "adding anticoagulant solution downstream of the separation step", respectively.

As a consequence, the conclusions made with respect to claim 1 of the main request apply in the same way to the subject-matter claim 1 of the first auxiliary request, and the first auxiliary request does also not comply with Article 76(1) EPC.

5. *Second auxiliary request*

The method of claim 1 according to the second auxiliary request comprises a two-stages separation process defined by features (a) and (c), in accordance with the two-stages portions A and B disclosed in the grand parent application and illustrated in its Figure 1. However, the intermediate step according to feature (b) of "adding anticoagulant solution to the separated platelet rich plasma (PRP) component in an amount sufficient to prevent clotting" is not disclosed in the

original application, let alone in the form of the claimed combination.

Although it is generally known to add anticoagulant during withdrawal of blood in order to prevent clotting (see page 3, lines 1 to 4 of WO-A-91/19561), the specific addition of anticoagulant in the separated PRP component to prevent clotting is not directly and unambiguously disclosed in the grand parent application. More specifically, in this document the prevention of clotting by addition of anticoagulant downstream of the first separator is only concerned with the red cell suspension obtained, but not at all with the PRP component. WO-A-91/19561 only mentions that it is desirable to add anticoagulant to the PRP in order to enhance storage and further separation characteristics of the PRP (see page 6, lines 31 to 33; page 18, lines 19 to 23 and page 24, lines 1 to 5).

Consequently, feature (b) and hence the subject-matter of claim 1 according to the second auxiliary request extends beyond the content of the earlier application as filed, contrary to the requirements of Article 76(1) EPC.

6. *Third auxiliary request*

The method defined in claim 1 according to the third auxiliary request comprises, again, a two-stages separation process recited by features (a) and (c), however, compared to the second auxiliary request, supplemented by additional information from the description.

In accordance with the invention as defined in claim 1 of the third auxiliary request, anticoagulant is added in two steps:

- first to the whole blood before the first separation in a reduced amount of 4% by volume (feature (a)), and
- then to the PRP component obtained after the first separation, in an amount sufficient to permit adequate storage (feature (b)).

All these features are validly supported as well by the grand parent application as filed (see page 19, lines 1 to 4; page 24, lines 14 to 20 and claim 16) as by the parent application as filed (see page 11, lines 29 to 33 of the published version).

Therefore, the subject-matter of claim 1 of the third auxiliary request does not extend beyond the content of the earlier applications from which the present divisional application emerges, in compliance with Article 76(1) EPC and the condition imposed by G 1/06.

7. *Remittal*

Since the decision under appeal was principally based on the grounds of Article 76(1) EPC, now removed, and since the claims presently on file have been substantially amended, the Board finds it appropriate to remit the case to the first instance for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance for further prosecution on the basis of claims 1 to 5 of the third auxiliary request filed during the oral proceedings.

The Registrar:

The Chairman:

V. Commare

T. Kriner