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**Datasheet for the decision
of 21 September 2011**

Case Number: T 1610/08 - 3.2.02

Application Number: 00912217.7

Publication Number: 1161269

IPC: A61M 1/36

Language of the proceedings: EN

Title of invention:

System for collecting platelets and other blood components

Patentee:

HAEMONETICS CORPORATION

Opponent:

CaridianBCT, Inc.

Headword:

-

Relevant legal provisions:

EPC Art. 83

RPBA Art. 15(2)

Relevant legal provisions (EPC 1973):

-

Keyword:

"Sufficiency of disclosure: no"

"Postponement of oral proceedings: no"

Decisions cited:

T 0032/85, T 0190/99, T 0123/06

Catchword:

-



Case Number: T 1610/08 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 21 September 2011

Appellant:
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 16 June 2008
revoking European patent No. 1161269 pursuant
to Article 102(1) EPC 1973.

Composition of the Board:

Chairman: M. Noël
Members: C. Körber
A. Pignatelli

Summary of Facts and Submissions

- I. On 16 June 2008 the Opposition Division posted its decision to revoke European patent No. 1161269.
- II. An appeal was lodged against this decision by the patentee by notice received on 19 August 2008, with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 24 October 2008.
- III. By communication of 20 June 2011, the Board summoned the parties to oral proceedings scheduled for 21 September 2011 and forwarded its provisional opinion to them.

The respondent's representative requested, by letters dated 28 June 2011 and 18 July 2011, that the oral proceedings be postponed.

The Board declined to postpone the oral proceedings for the reasons given below (point 3).

- IV. At the oral proceedings held on 21 September 2011, the final requests of the parties were as follows:

The appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the claims according to the main or the first auxiliary request, both filed with letter dated 19 August 2011.

The respondent (opponent) requested that the appeal be dismissed.

V. Claim 1 of the main request reads:

"1. A system for collecting a fluid component of intermediate specific gravity, mixed with a fluid component of lower specific gravity, the system comprising:
a centrifuge rotor (21);
a flow-control arrangement (33, 22, 23, 98, 27) which introduces whole blood into the centrifuge rotor and removes blood components from the centrifuge rotor; a spinner (80) which rotates the rotor at more than one speed; and
a controller (20) for causing the spinner to rotate the rotor at a first speed so as to separate the blood into a first component (91), a second component (93) and a third component (92), the first component having the lowest specific gravity, the second component being located, while the rotor is being spun, outside of the first component and having the highest specific gravity, and the third component being located, while the rotor is being spun, between the first and the second components and having an intermediate specific gravity, characterised in that the controller is constructed for causing the rotor's speed of rotation to be altered so as to cause the third component (92) to mix with the first component (91), and for causing the flow-control arrangement to remove from the rotor a portion of the first component (91) containing the third component (92);
wherein platelets suspended in plasma are collected, the first component (91) being primarily plasma, the second component (93) being located, while the rotor (21) is being spun, outside of the first component (91)

and being primarily red blood cells, and the third component (92) being located, while the rotor (21) is being spun, between the first (91) and the second (93) components and including platelets, and the flow control arrangement (33, 22, 23, 98, 27) removing from the rotor (21) a portion of the plasma containing platelets."

Claim 1 of the first auxiliary request comprises the following additional feature at its end:

"wherein the controller causes the flow-control arrangement to remove some of the first component before the third component is mixed with the first component; and
wherein the system further comprises a plasma-volume determination sensor (97) in communication with the controller, the plasma-volume determination sensor determining the volume of the first component in the rotor, and the controller removing a portion of the first component based on the determined volume of the first component."

VI. The appellant's arguments are summarised as follows:

In view of the skilled person's general technical knowledge there was no need to indicate any specific values of the "first speed" of rotation required in order to achieve a separation of the blood into the three components defined in the claim. Since the claim defined that the speed of rotation was to be altered so as to cause the third component to mix with the first component, it was clear that only a decrease and not an increase in speed could be meant. According to T 190/99

a patent should be construed by a mind willing to understand, and interpretations of a claim which were illogical and did not make technical sense should be ruled out. Consequently, the possibility of a remixing of all three components, as occurring upon a complete stopping of the centrifuge, was clearly excluded. In order to achieve the mixing of the first and third components, only a single parameter, viz. the speed of rotation, had to be determined, and this did not represent an undue burden for the person skilled in the art. Accordingly, the present case was quite different from the situation underlying T 32/85 wherein a particular choice of numerous parameters had to be made.

Concrete values of a suitable centrifuge speed reduction were generally known to the skilled person and could also be derived from the prior art, for instance from US-A-5 505 685 (e.g. column 12, lines 52 to 56). Moreover the patent itself disclosed in paragraph [0015] two examples of changing the speed of rotation, namely sharply or gradually. Accordingly, at least one way was clearly indicated in the patent specification enabling the skilled person to carry out the invention. The exact magnitudes of the speed or rotation depended on the specific sample conditions and could be determined for each case without any difficulties. The skilled person was also aware of how to keep the red blood cells separate, i.e. of how the speed was to be "slowed sufficiently" in order to avoid a remixing of all three components.

VII. The respondent's argument are summarised as follows:

Claim 1 according to all requests was very broad in that it simply required an alteration of the rotor's speed (increase or decrease by any amount or rate of the change) in order to achieve a mixing of the first and third components, plasma and platelets (without giving any indication of the degree of mixing or excluding that the second component, red blood cells, was also present in the mixture). Not a single example quantifying the rotational speed changes was given anywhere in the patent. From the specification (paragraph [0015]) it could only be derived that the desired effect was to be achieved by abruptly changing the speed or by reducing it more slowly. No example was given of what was considered "abrupt". Due to the large number of possibilities of changing the speed (decrease or increase from different starting values, abruptly or slowly, by a small or a large amount) for different types of centrifuges (with different radial distances from the centre of rotation), extensive experiments would be needed to determine the speed alteration that was required. Such a degree of trial and error amounted to an undue burden. Moreover, the broad wording of the claim also covered the complete stopping of the centrifuge, resulting in a re-mixing of all three components. Accordingly, the skilled person would not be able to achieve the object of the invention across the full scope of the claim.

The request for postponement of the oral proceedings was justified since the representative of the respondent had already firmly booked a holiday. He could not be substituted because the party had built up

a particular trust with the representative in view of a long-standing personal representation of his client, because none of his partners knew anything about the opponent's business or technology and bringing any one of them up to speed would cause additional costs to the party, and finally because his knowledge of the preceding proceedings before the Opposition Division was unique and not substitutable. A letter of the Director of Intellectual Property of the respondent dated 14 July 2011 was filed to prove that a relationship of particular trust had been built up with the representative.

Reasons for the Decision

1. The appeal is admissible.
2. Sufficiency of disclosure

Article 83 EPC requires that the European patent application discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. In accordance with the established jurisprudence of the Boards of Appeal (see "Case Law of the Boards of Appeal of the EPO", 6th edition (2010), II.A.3 and II.A.4), the requirements of Article 83 EPC are only met:

(i) if at least one way is clearly indicated in the patent specification enabling the skilled person to carry out the invention, and

(ii) if the disclosure allows the invention to be performed in the whole area claimed

(iii) without undue burden, applying common general knowledge.

Claim 1 of the main request as well as of the first auxiliary request is directed to a system for collecting a fluid component of intermediate specific gravity, mixed with a fluid component of lower specific gravity, which comprises a number of known structural apparatus features as defined in the preamble of these claims. The preamble further defines a "first speed" of the rotor so as to separate three components of the fluid, blood, according to their specific gravity, with the third component [including platelets] being located between the first component [primarily plasma] and the second component, which has the highest specific gravity [primarily red blood cells]. The Board accepts that the skilled person could determine this first speed of rotation for a given rotor based on general knowledge without undue burden.

In the characterising portion, the controller is defined in terms of a certain function or result to be achieved, viz. being "constructed for causing the rotor's speed of rotation to be altered so as to cause the third component (92) to mix with the first component (91)". This functional feature is in fact presented in the appellant's statement of grounds of appeal as the key element of the claimed invention.

In principle, the rotor's first speed of rotation may be "altered" in many different ways, e.g. increased or

decreased, step-wise, continuously at various rates, or even non-linearly, and by a certain amount or magnitude. Taking into account the desired result of mixing the platelets with the plasma, the skilled person could be expected to exclude the possibility of an increase in speed of rotation since this would rather result in a further separation of the components. Nevertheless, this leaves a practically unlimited number of possibilities of altering the speed. Even a complete stopping of the centrifuge would fall under the scope of the claim. The question therefore arises whether the skilled person has been given sufficient information to enable him to select without undue burden from these possibilities of altering the speed of rotation those achieving the desired result of mixing the two components.

The description of the patent in suit gives the skilled person little further guidance in this respect. In paragraph [0015] it is merely stated that "the platelets 92 may be mixed with the remaining plasma by sharply changing the speed of rotation of the rotor 21", but that "the rotor's speed must not be altered so radically and quickly as to cause the red blood cells as well to mix with the other components". Alternatively, the speed of rotation "may be slowed sufficiently -- although not necessarily sharply -- so that the platelets mix with the plasma but the red blood cells remain separate". Paragraph [0021] simply repeats that the speed of the rotor may be changed "rapidly".

From this it may be concluded that at least two parameters are of importance with respect to the

alteration of the speed of rotation, namely the rate of change ("slowly" or "rapidly") and the amount or magnitude of the alteration ("sufficiently"). However, the entire patent fails to indicate a single example or value of either one of these two parameters.

In order to meet the requirement of sufficiency of disclosure, a detailed description of at least one way of carrying out the invention must be given. A feature essential for carrying out the invention must be disclosed in sufficient detail to render it apparent to the skilled person how to put the invention into practice. In principle, a single example may be sufficient. Where the claim covers a broad field, as in the present case, it is even necessary that the description gives a number of examples or describes alternative embodiments or variations extending over the area protected by the claim (see "Case Law of the Boards of Appeal of the EPO", 6th edition (2010), II.A.3.b) and II.A.3.c)). When there is no example at all, as in the present case, these requirements are clearly not met.

When trying to carry out the invention as claimed, the skilled person's situation is further aggravated by the fact that that the result to be achieved, "mixing", is not well defined since the degree of mixing to be obtained is nowhere indicated. Moreover, the definition in claim 1 does not exclude that the second component, red blood cells, is also present in the mixture of platelets and plasma. Furthermore, the parameter "speed of rotation" is not the only governing parameter of a centrifugation process. Such a process is normally characterised by the "centrifugal force", usually

indicated in terms of a multiple of the gravitational force or acceleration, "g" or "G", which also depends on the distance from the point of rotation, which is generally different for each type of rotor.

Consequently, to carry out the claimed invention the skilled person, in each single case, is faced with the problem of determining, for a given rotor, suitable values of at least two parameters, viz. rate and magnitude of the alteration of speed of rotation, in order to achieve a result which in itself is imprecisely defined. However, neither the common general knowledge nor the patent in suit provides him with any information to guide him in successfully performing this task. Thus, the skilled person does not have at his disposal any guidance leading necessarily and directly towards success through the evaluation of initial failures so that he could only establish by trial and error in each individual case whether or not a particular choice of possible alternatives from among the various parameters would provide the result to be achieved by the claimed device, which amounts to an undue burden (cf. T 123/06, point 2.2 of the Reasons).

Contrary to the appellant's view and point 1.2 of the impugned decision, document US-A-5 505 685, which is a separate patent specification not cited in the patent in suit, cannot be used to document common general knowledge relevant for assessing sufficiency of disclosure (see "Case Law of the Boards of Appeal of the EPO", 6th edition (2010), II.A.2.a), penultimate paragraph).

From the above it follows that the requirements of Article 83 EPC are not fulfilled.

3. Request for postponement of oral proceedings

The respondent's request for postponement of the oral proceedings was considered in the light of the Rules of Procedure of the Boards of Appeal (RPBA) and the Notice of the Vice-President of Directorate-General 3 dated 16 July 2007 concerning oral proceedings before the boards of appeal of the EPO (OJ EPO 2007, Special Edition No. 3, 115), referred to as the "Notice" hereinafter.

According to Article 15(2) RPBA, the Board has a discretion to allow exceptionally a change of date for oral proceedings. In exercising its discretion, the Board has to take into account the internal organisational burden of the Board and the guidelines given to the public in the Notice.

The Notice (point 2.1) lists holidays which have been firmly booked before the summons as a potential serious reason for a representative to request a change of date for oral proceedings.

Point 2.1 of the Notice has to be balanced against point 2.3 of the Notice, according to which every request for fixing another date for oral proceedings should contain a statement why another representative within the meaning of Articles 133(3) or 134 EPC cannot substitute for the representative prevented from attending the oral proceedings. Point 2.3 of the Notice thus makes it clear that substitution of a

representative is a possible alternative to postponement.

The Board is of the opinion that the circumstances indicated by the respondent with respect to point 2.3 are in fact common to all cases in which substitution is involved. When a party is represented it is a normal situation that the party trusts its representative. The same is true for the point that substitution is likely to cause additional costs to the party. The new representative normally has to prepare the case he takes over and normally has to be paid for his work. Also the fact that the experience acquired during the preceding opposition proceedings is unique is the usual situation when a new representative must take over the representation during an appeal in an inter partes case.

If point 2.3 of the Notice was to be interpreted to mean that the reasons mentioned by the respondent would fulfil the criteria for excluding the possibility of a substitution, then the provision could never be applied and would be devoid of any meaning. This cannot reasonably be considered to have been the intention of the drafter.

In the Board's view, only **extraordinary** circumstances, i.e. those which are not common to every case of substitution, should be accepted.

In general, a party can trust other representatives. The respondent's letter of 14 July 2011 shows that this is also the case in the present proceedings. It was not submitted that it was impossible for other

representatives to do the necessary preparation. Further, the present case does not imply special technical difficulties which might prevent the substitution of one representative having a background in the field of medical technology by another one of the numerous representatives of similar background from the same association of representatives. Nor have any particular technical, factual or legal circumstances been asserted which might warrant a different finding.

As far as costs are concerned, it is the decision of the representative in charge of the case whether he will pay the substitute himself or charge the costs to his client. In any case, this is not a relevant factor for the proceedings before the EPO because it does not affect the feasibility of the substitution per se. It simply means that additional costs might arise but does not imply that the party or the representative cannot afford these additional costs.

While experience of foregoing opposition proceedings can be useful, it is not necessary in order to represent a party competently before the board of appeal. No reasons have been submitted that make this case different.

The Board has taken into account the fact that the appellant had indicated that it would also be convenient to him for the oral proceedings to be rescheduled (even though he did not file a request in this respect). However, this is only one aspect among others, as indicated above, and cannot not outweigh the constraints of the internal organisational burden for the Board.

For the above reasons, the Board considers that the submitted reasons do not amount to extraordinary circumstances that are not common to all cases of substitution. A party's general desire to be represented by a specific member of an association of representatives is not considered sufficient ground for changing the date for oral proceedings. Otherwise the provision according to point 2.3 of the Notice would have hardly any significance in practice.

The Board therefore refused the respondent's request for postponement of the oral proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

D. Hampe

M. Noël