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**D E C I S I O N**  
**of 16 May 2000**

**Case Number:** T 0731/98 - 3.2.2

**Application Number:** 88307080.7

**Publication Number:** 0301913

**IPC:** A61B 5/14

**Language of the proceedings:** EN

**Title of invention:**  
Blood aspiration assembly

**Patentee:**  
Lynn, Lawrence A.

**Opponent:**  
pvb medizintechnik GmbH

**Headword:**  
-

**Relevant legal provisions:**  
EPC Art. 56

**Keyword:**  
"Inventive step (yes)"

**Decisions cited:**  
-

**Catchword:**  
-



Case Number: T 0731/98 - 3.2.2

**D E C I S I O N**  
**of the Technical Board of Appeal 3.2.2**  
**of 16 May 2000**

**Appellant:** pvb medizintechnik GmbH  
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**Respondent:** Lynn, Lawrence A.  
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**Representative:** Goodenough, Nigel  
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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 13 May 1998  
rejecting the opposition filed against European  
patent No. 0 301 913 pursuant to Article 102(2)  
EPC.

**Composition of the Board:**

**Chairman:** W. D. Weiß  
**Members:** M. G. Noël  
R. T. Menapace

## Summary of Facts and Submissions

I. Following an opposition filed by the appellant against European patent No. 0 301 913, the Opposition Division decided on 13 May 1998 to reject the opposition, after having considered the state of the art represented in particular by the following documents:

D1: US-A-4 673 386

D2: "Prospective randomized evaluation of two methods of drawing coagulation studies from heparinized arterial lines "by K. Cannon, K. A. Mitchell and T. C. Fabian, Heart and Lung, July 1985, vol. 14, No. 4, pages 392-395.

II. Claim 1 as granted reads as follows:

"An assembly (20) for use with a blood access device (174) inserted in a patient's blood vessel for obtaining undiluted blood samples, the assembly comprising: a tubular portion (125,110,50) which, in use, may be filled with a resident fluid, the tubular portion being connectable at one end to the blood access device and including a blood receiver having a chamber (110), the blood receiver permitting a separate blood removal device (185) to repetitively access the chamber (110); and a variable volume reservoir (61) connected to the tubular portion, the reservoir having sufficient volume to selectively receive a first volume (X) of fluid from the tubular portion sufficient to ensure that undiluted blood is present in said chamber characterised in that the internal volume of the portion of the assembly lying between the chamber (110) and the reservoir (61) is such that when said first

volume (X) is received by the reservoir the entire volume of mixed resident fluid and blood created by the flow of the first volume (X) in the assembly is contained within the said portion of the assembly between the chamber and the reservoir."

- III. The appellant lodged an appeal on 20 July 1998 against the first instance's decision and filed a statement of grounds on 21 September 1998.

The respondent (proprietor of the patent) replied to the appellant's contentions on 4 March 1999 and on 27 April 2000, respectively.

- IV. Oral proceedings were held on 16 May 2000, at the end of which the requests were as follows:

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

The respondent requested that the appeal be dismissed.

- V. The parties argued as follows:

(i) the appellant:

- In document D1, the piston of the fluid storage mechanism 11 provided for facilitating withdrawal of blood and temporarily storing the fluid residing in the circuit can be retracted in such a way that the volume of mixed supply fluid and blood remains in the tubing portion between the port 53 for taking undiluted blood samples and said fluid storage mechanism. The position of the interface only depends on the manner the blood

sampler device is used. Consequently, document D1 discloses not only the features in the preamble of claim 1 but also, implicitly, the features in the characterizing portion thereof. As a result, the subject-matter of claim 1 is not novel, and at least not inventive with respect to the disclosure of document D1.

- In order to avoid with certainty that no blood is drawn into the fluid storage mechanism according to D1, the skilled person will obviously provide the tubing portion between said storage mechanism and the removal port with sufficient length to retain the entire volume of mixed fluid and blood within said portion, as suggested by Figure 1 of document D2 which discloses a blood sampling kit with a suitable length of tubing between a proximal stopcock for taking undiluted blood and a distal stopcock for drawing the fluid by means of appropriate syringes. Therefore, the subject-matter of claim 1 is also not inventive, having regard to the combination of documents D1 and D2.

(ii) the respondent:

The appellant's interpretation of document D1 is wrong since a withdrawal of fluid of at least five or six times the dead volume from the insertion site to the blood sampling port is required, to be assured that a reliable undiluted blood sample is obtained. This would not be possible in the assembly according to document D1 because of the short tubing length (see Figure 2) between the storage mechanism and the sampling port. For the same reason, a volume of fluid and blood mixture

would not be prevented from entering the storage mechanism. Therefore, the characterising features of claim 1 are not disclosed by document D1.

- In document D2, the drawing method and the dimensional characteristics of the assembly given in relation to Figure 1 and Table II imply that the fluid withdrawn at the distal stopcock amounts to only four times the volume of the dead space between the patient and the sampling port at the proximal stopcock. According to the patent, such withdrawal volume is deemed to be insufficient to assure accurate results of the patient's actual hematocite value. Moreover, having regard to the volumes indicated in document D2, the fluid and blood mixture interface will inevitably attain the reservoir formed by the syringe connected to the distal stopcock. Therefore, also document D2 fails to disclose the characterising features of claim 1.

### **Reasons for the Decision**

1. The appeal is admissible.
2. *Closest prior art and novelty of claim 1*
  - 2.1 Document D1 represents the closest prior art document. It discloses all the features contained in the precharacterising portion of claim 1, in particular a blood sampler device comprising, in an arterial line 40 supplied with fluid under pressure, a three-way valve 49 having a blood sampling port 53 and a storage mechanism 11 provided with a piston 15 retractable in a

chamber 40 so as to draw and temporarily store the volume of fluid present in the tubing from the injection site. Therefore, the body of the three-way valve has the function of the blood receiving chamber 110 in the patent, whereas the storage mechanism plays the role of the variable volume reservoir 61 in the patent.

- 2.2 The problem addressed in document D1 is principally to avoid unnecessary discarding of blood by sampling at port 53 blood clear of supply fluid and therefore representative of the actual patient's blood (cf. column 1, lines 59 to 68). However, contrary to the present patent, document D1 does not require that blood should be prevented from entering the storage mechanism as supply fluid is drawn into the storage chamber. On the contrary, document D1 clearly states (column 3, lines 21 to 26) that the piston may be retracted sufficiently to also draw blood from the patient through the valve and into the chamber within the storage mechanism. Thus, the disclosure of document D1 is restricted to the features contained in the preamble of claim 1.

The appellant's interpretation of document D1 according to which retraction of the piston within the storage mechanism can be adjusted so as to maintain the position of the fluid and blood interface within the tubing portion in the way as claimed, is not accepted by the Board since this interpretation would differ substantially from the general concept disclosed in this document, according to which it is clearly recommended also to draw blood into the storage mechanism so as to be sure that blood sampled at port 53 does not include an unrepresentative quantity

of fluid (cf. column 3, lines 36 to 41).

2.3 Since none of the cited documents comes closer to the invention than does document D1, the subject-matter of claim 1 must be regarded as novel within the meaning of Article 54(1) EPC.

3. Inventive step

3.1 The characterising portion of claim 1 represents the solution of the specific problem of avoiding any presence of blood in the reservoir for preventing the formation of blood clots as well as eliminating most of blood through discard (patent, column 6, lines 43 to 48).

As explained in the patent specification (cf. column 6, lines 20 to 28) when the reservoir is filled and a volume of fluid has entered the reservoir, the column of fluid within the assembly comprises three basic segments which progressively merge together: a distal segment consisting of substantially undiluted blood, an intermediate segment of blood mixed with resident fluid and a proximal segment of resident fluid which contains essentially no blood. Thus, blood replaces all resident fluid within the sampling chamber but does not enter the reservoir during withdrawal (column 12, lines 53 to 55).

Although the characterising features of claim 1 are drafted in functional terms, the device as claimed is sufficiently defined since the relationship between the volume of the portion of the assembly between the receiving chamber and the reservoir on the one hand, and the volume and the position of the mixed resident



fluid and blood interface within said portion on the other hand, provides the skilled person with sufficient information for determining the dimensional characteristics of the different parts of the assembly as a whole.

3.2 As was already considered before, the disclosure of document D1 teaches away from the present invention since it does not prevent blood from entering the storage chamber, with the risk of giving rise to clot formation. Besides, the volume of the tubing portion between the storage chamber and the sampling port plays no role in this document. Therefore, the skilled person would not find therein any incitement to increase the dimensions of the tubing portion so as to form, like in the present patent, a capacitance segment distal to the sampling port suitable to provisorily store the initial discarded volume of blood-resident fluid admixture.

3.3 Document D2 discloses a study evaluating two methods of drawing clinically reliable coagulation studies from heparinized arterial lines. While method A (Table I) results in discarding significant amounts of blood, method B (Table II) involves, like the present patent, no blood loss and, for this reason, it is the preferred procedure. The step-by-step description of the method B is made in relation to Figure 1 which illustrates a suitable arterial pressure monitoring kit, comprising two separate stopcocks inserted in a tubing circuit connected to a pressure bag containing an heparin solution. The proximal stopcock near to the insertion site in the patient is provided with a port for sampling blood with a syringe whereas the distal stopcock is provided with a permanently placed 5 ml Luer-lock syringe thus having the function of the

variable volume reservoir in the patent.

According to the steps listed in Table II, the dead space from the insertion site to the distal stopcock (most distant to the patient) amounts to 4 ml, which includes the dead space of 1 ml from insertion site to the proximal stopcock (see Table I). Therefore, when a volume of fluid equal to the overall dead space (4 ml) is withdrawn at the distal stopcock (step No. 3 in Table II), this volume represents four times the volume of tubing (1 ml) between the patient and the sampling port which, according to the patent (column 3, lines 4 to 20) is insufficient to obtain reliable blood samples, i.e. which are completely free of flush fluid, for measuring both blood gas values and hematocrit concentrations. Instead, the patent imposes an aspirated volume of at least six times the dead space up to the sampling port, in conformity with the report referred to in column 3 of the patent ("Errors in Intraoperative Hematocrit Determination" vol. 45, 1976, see in particular page 359). This requirement cannot be actually attained by the arrangement disclosed in document D2.

Since, according to document D2, a volume of fluid equal to the volume of the dead space is withdrawn, the blood-resident fluid interface originally present at the insertion site will be progressively aspirated and displaced towards the distal stopcock and through the syringe-reservoir. Therefore, blood will necessarily enter the syringe, which is contrary to the problem addressed by the patent, the more since the total capacity of the syringe (5 ml) is greater than the dead space.

It results therefrom that document D2 neither discloses nor suggests the essential features of the invention, according to which the entire volume of mixture resident fluid and blood is contained within the portion of assembly between the chamber and the reservoir, so as to prevent any blood entering the reservoir.

- 3.4 Since no other document is more relevant than document D2 the subject-matter of claim 1 must be regarded as inventive over the state of the art, in particular over the combination of documents D1 and D2.

### **Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß