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**D E C I S I O N**  
**of 4 November 1998**

**Case Number:** T 0412/95 - 3.2.2

**Application Number:** 86300574.0

**Publication Number:** 0193279

**IPC:** A61B 5/14

**Language of the proceedings:** EN

**Title of invention:**  
A vacuum blood-collection tube

**Patentee:**  
Sekisui Kagaku Kogyo Kabushiki Kaisha

**Opponent:**  
Becton, Dickinson and Company

**Headword:**  
-

**Relevant legal provisions:**  
EPC Art. 52, 56, 104, 114  
EPC R. 55

**Keyword:**  
"Claim 1 - inventive step (yes)"  
"Late-filed documents; remitted to the first instance (yes)"  
"Apportionment of costs (no)"

**Decisions cited:**  
T 0156/84

**Catchword:**  
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## Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal received on 8 May 1995 against the decision of the opposition division dispatched on 8 March 1995 to reject the opposition against patent No. 193 279. The statement setting out the grounds for appeal was received on 17 July 1995. The fee for appeal was paid on 8 May 1995.
- II. Opposition was filed against the patent as a whole and based on Article 100(a) EPC for lack of inventive step. The Opposition Division held that the grounds for opposition mentioned in Article 100(a) EPC did not prejudice the maintenance of the patent having regard to the following documents
- (1) JP-A-66551/84
  - (11) US-A-4 420 517
- III. During the appeal procedure the appellant submitted the following further documents:
- (a): together with the statement of grounds for appeal:
    - (12) US-A-3 746 196
    - (13) US-4-397 318
  - (b):
    - (14) JP-A-58-195151
    - (15) JP-A-58-195152,
- first cited with letter of 31 July 1996;

the translations into English, 14-1 and 15-1 respectively, were delivered on 21 August 1998;

(c) with letter of 22 September 1998:

(16) Polymer Handbook, John Wiley International Publications, 1975, pages III-229 to III-240.

Following a request of both parties, oral proceedings were held on 4 November 1998 at the end of which following requests were submitted:

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

The respondent (patent proprietor) requested that the appeal be dismissed and that the patent be maintained as granted (main request) or that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the documents filed on 16 May 1994 (first auxiliary request) or on the basis of the two auxiliary requests filed by letter of 6 December 1996. He also requested an apportionment of costs.

IV. The independent claim according to the main submission as granted reads as follows:

"A vacuum blood-collection tube comprising a tube-shaped vessel having an opening through which air can be removed, and a plug that makes the opening air-tight to maintain low-pressure conditions inside the said vessel, said vessel being fabricated from polyethyleneterephthalate, a copolymer of polyethyleneterephthalate, or an acrylonitrile resin, and the inner walls of said vessel incorporating

- (a) a hydrophilic substance that is either difficult or impossible to dissolve in water and that is capable of preventing blood clots from adhering to the inner walls of said tube;
- (b) an adsorptive inorganic substance capable of accelerating blood coagulation and selected from glass, silica, kaolin, cerite and bentonite; and
- (c) a contact-enhancing substance capable of improving contact between the adsorptive inorganic substance (b) and blood said substance c) being selected from ethyleneglycol, glycerin, sorbitol, polyethyleneoxide, polyvinylalcohol, polyvinylpyrrolidone, sodium polyacrylate, polyethyleneimine, sodium alginate, starch, pullulan, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, carboxymethylcellulose, cellulose acetate phthalate, gum arabic, gum tragacanth, locust bean gum, guar gum, pectin, carrageenan, furcellaran, glue, gelatin and casein."

V. The appellant argued as follows.

Documents (14-1) and (15-1) are relevant because they constitute the nearest prior art and therefore they should be admitted in the proceedings notwithstanding the fact that they have been filed in a late stage of the procedure.

Said documents should be dealt with in the present appeal. A remittal to the first instance is not justified because said documents originate from the patentee itself. The patentee has had already sufficient time to deal with them. The request for remittal is only a means for prolonging the life of the patent.

An award of costs due to the late-filing in favour of the respondent is not justified because the late filing was due to the difficulty to access and evaluate the Japanese patent data base. Moreover these documents originated from the same applicant of the patent in suit. Also one of the inventors is the same.

Claim 1 of the main request is not inventive having regard to document (1) alone or together with document (11). Document (1) addresses the problem of:

- (a) adhesion of clots to the internal wall of the container and the problem of:
- (b) promoting coagulation, see page 3, from line 4, and from line 7 from the bottom, paragraph bridging pages 4 and 5.

The solution is given at page 5, second and third paragraph and consists in providing specific substances for preventing adhesion and promoting coagulation.

The problem of the patent in the light of document (1) is to improve the rate of coagulation which in document (1) is still 1 hour and 20 seconds. This problem is addressed in document (11), column 1, lines 20 to 26.

The solution is given at column 2, lines 1 to 3 by means of a carrier for the silica, the polyvinylpyrrolidone, which dissolves in liquid carrying the insoluble silica particles into solution and promotes the clotting by favouring the contact between the silica particles and the liquid. See also column 2, line 26. In this manner the coagulation time is reduced.

Document (11) discloses a vacuum tube of the same type of the invention. The further feature of selecting a material for the tube which is sufficiently gas impermeable belongs to the general knowledge of the person skilled in the art.

The respondent argued as follows.

Documents (14-1) and (15-1) should not be admitted in the proceedings having been filed too late and not relevant since they fail to disclose vacuum tubes and to address the problem of storage stability of the serum.

In the case said documents are admitted in the proceedings the case should be remitted to the first instance for a first evaluation in order to have the possibility of a revision.

The late submission justifies an apportionment of costs under Article 104 EPC for the additional expenses caused thereby.

Claim 1 of the main submission is inventive with respect to the further documents of the state of the art. In particular, document (1) leads away from the invention because the substances which are enumerated as being capable of preventing adhesion of blood clots to the wall, listed on page 5, are not substances which simultaneously are hydrophilic and either difficult or impossible to dissolve in water as requested by feature (a) of the claim, compare page 4, from line 33 of the patent in suit with document (1), page 5. Furthermore document (1) does not address the problem of storage stability and it does not disclose vacuum tubes. According to the invention, a layer of thixotropic material which separates the serum from the clotted blood reliably adheres to the layer covering

the wall of the tube preventing seeping of fluid along the wall and surface ensuring its sealing function. In this manner the tube according to the patent in suit assures a quick blood separation together with a long storage time.

### **Reasons for the Decision**

1. The appeal is admissible.

2. *Procedural matter*

2.1 The documents D12 and D13 have been cited by the appellant in the grounds of appeal for the first time as an immediate reaction with the aim to close gaps in its line of arguments which became evident by the reasons of the decision under appeal. By the introduction of these documents only the previously used line of arguments is completed and not an entirely new case opened by the appellant. Furthermore, the respondent did not contest the introduction of these documents into the proceedings.

The Board, therefore, has considered these documents as not being cited late and therefore has included them in the proceeding.

2.2 The documents D14, D15 and D16 , to which the respondent had the opportunity to present its comments, have been cited more than one year after the submission of the grounds for appeal and therefore clearly too late. Since the Board, however, considers these documents to be prima facie highly relevant with respect to the subject-matter of the patent in suit, these documents should not be disregarded in application of the provisions of Article 114(2) EPC (see T 156/84, OJ EPO 1988, 372) but be introduced into



the proceedings in the case that the timely cited documents, in particular D1, D11, D12 and D13, are found not to endanger the allowability of Claim 1 according to the main request.

3. *Inventive step with respect to timely cited prior art*

3.1 Document D1, represented by its translation into the English language, is the closest prior art.

This document discloses a blood-collection tube comprising a tube-shaped vessel having an opening, the inner walls of said vessel incorporating

- (a) a substance to which blood components adhere with difficulty; and
- (b) an absorptive inorganic substance capable of accelerating blood coagulation and selected from glass or silica (see the paragraph bridging the pages 5 and 6).

The list of substances which are preferably used to serve for the function (a) (see page 5, third paragraph) includes substances which are water soluble, others which are water insoluble, hydrophobic and hydrophilic substances.

The subject-matter of claim 1 according to the main request differs from the disclosure of the above cited document in that air can be removed from the tube, and a plug is provided that makes the opening airtight to maintain low-pressure conditions inside the said vessel, said vessel is fabricated from polyethylenterephthalate, the substance serving for the function (a) is obligatorily selected to be hydrophilic and either difficult or impossible to dissolve in water, and that the inner walls additionally

incorporate a contact-enhancing substance (c) capable of improving contact between the absorptive inorganic substance (b) and blood, said substance (c) being collected from ethyleneglycol, glycerin, sorbitol, polyethyleneoxide, polyvinylalcohol, polyvinylpyrrolidone, sodium polyacrylate, polyethyleneimine, sodium alginate, starch, pullulan, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, carboxymethylcellulose, cellulose acetate phthalate, gum arabic, gum tragacanth, locust bean gum, guar gum, pectin, carrageenan, furcellaran, glue, gelatin and casein.

- 3.2 Starting from document (1), the problem to be solved by the invention consists in providing a good blood coagulation while warranting a prolonged storage of the serum in the same vessel used for centrifugation.

Feature (c) contributes to accelerating blood coagulation, whereas the relatively low permeability of the material of the tube together with the sealing plug increase the storage time in the vessel after centrifugation. Furthermore the low hydrophilicity of the material of the tube warrants a reliable separation between the serum and the blood clot because the partitioning agent between serum and clot can strongly adhere to the wall of the container. In this way the serum can be stored for long periods without deterioration.

- 3.3 The teaching of document (1) alone or in combination with the teaching of the further documents of the prior art taken in consideration, in particular of document (11), do not give any hint which can lead in an obvious way to the invention as claimed. They fail in particular to disclose the problem of long time storage and the material of the vessel.

Document (11) discloses a vacuum blood-collection tube comprising a tube-shaped vessel having an opening through which air can be removed, and a plug that makes the opening air-tight to maintain low pressure conditions inside said vessel (see figure and description, column 37 lines 43 to 47), an adsorptive inorganic substance capable of accelerating blood coagulation and selected from glass, silica, kaolin and bentonite (column 1, lines 22 and 23); and a contact-enhancing substance capable of improving contact between the adsorptive inorganic substance and blood, said substance being for example polyvinylpyrrolidone, methylcellulose and carboxymethylcellulose (column 2, lines 28 to 32).

The subject-matter of claim 1 distinguishes from the above cited document by the features that said vessel is fabricated from polyethyleneterephthalate, a copolymer of polyethyleneterephthalate, or an acrylonitrile resin and in that the inner walls of said vessel incorporate a hydrophilic substance that is either difficult or impossible to dissolve in water and that is capable of preventing blood clots from adhering to the inner walls of said tube.

Document (12) does not belong to the field of the invention concerning a polycarbonate container for medical substances having a silicon layer in the inner surface.

Document (13) discloses a polypropylene container for blood which has been treated with a silicone coating.

The appellant argues that choosing a suitable material for the tube in order to have a sufficient high grade of gas impermeability is a common feature in the field.

Furthermore it argues that document (11) discloses a vacuum tube and a contact enhancing substance according to the invention as claimed in claim 1 of the main submission.

However, the cited documents do not contain any hint to address the problem of long time storage nor can lead in an obvious way to the particular choice of the material of the tube disclosed by the invention.

Accordingly claim 1 of the main submission has to be considered inventive with regard to the documents (1), (11), (12) and (13).

4. *Remittal to the first instance*

Since, according to the arguments set out above, the timely cited documents alone cannot endanger the allowability of the main request, the late filed documents D14, D15 and D16 have to be included in the considerations before a final decision can be reached.

By citing these prima facie highly relevant documents, however, the appellant has presented an entirely fresh case quite different from that on which the contested decision is based. Following the steady jurisprudence of the board of appeal (see Case Law of the Board of Appeal, 1996, page 232, point 6.9.1 ff), the case, under these circumstances, should be remitted to the department of first instance in order to warrant a fair judgement by two instances.

5. *Apportionment of costs*

The fact that the remittal to the first instance has been caused by the late submission of highly relevant documents by the appellant would in principle justify an apportionment of costs in favour of the respondent.

In the present case, however the documents D14 and D15 originate from the respondent itself, even one of the inventors being in common with the patent in suit. Since these two documents can be considered as relevant state of the art which can be regarded as useful for the understanding of the invention and which, according to Rule 27(b) EPC, the applicant is obliged to cite and evaluate in the description.

The Board, therefore, concludes that the responsibility for the protraction of the proceedings which is caused by this late submission lies equally on the shoulders of the appellant and the respondent.

Consequently, each party should bear its own costs.

## Order

### For these reasons it is decided that:

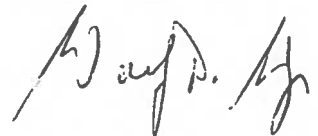
1. The decision under appeal is set aside.
2. The case is remitted to the Opposition Division for further prosecution.
3. The request for apportionment of costs is rejected.

The Registrar:



S. Fabiani

The Chairman:



W. D. Weiß

