

Internal distribution code:

- (A) Publication in OJ
(B) To Chairmen and Members
(C) To Chairmen
(D) No distribution

D E C I S I O N
of 24 January 2005

Case Number: T 1064/02 - 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. 56

Keyword:
"Inventive step (no) "

Decisions cited:

-

Catchword:

-



Case Number: T 1064/02 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 24 January 2005

Appellant: SEKISUI KAGAKU KOGYO KABUSHIKI KAISHA
(Proprietor of the patent) 4-4 Nishitemma 2-chome
Kita-ku
Osaka 530 (JP)

Representative: Nash, David Allan
HASELTINE LAKE
Redcliff Quay
120 Redcliff Street
Bristol BS1 6HU (GB)

Respondent: Becton, Dickinson and Company
(Opponent) One Becton Drive
Franklin Lakes, NJ 07417-1880 (US)

Representative: von Kreisler, Alek, Dipl.-Chem.
Patentanwälte
von Kreisler-Selting-Werner
Postfach 10 22 41
D-50462 Köln (DE)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 8 August 2002
revoking European patent No. 0193279 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: T. K. H. Kriner
Members: D. Valle
E. J. Dufrasne

Summary of Facts and Submissions

I. The appellant (patentee) lodged an appeal on 4 October 2002 against the decision of the opposition division posted on 8 August 2002 on the revocation of the European patent EP-B-193279. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 9 December 2002.

II. The Opposition division held that the ground for opposition mentioned in Article 100(a) EPC, i.e. lack of inventive step, prejudiced the maintenance of the patent.

III. The following documents introduced during the opposition procedure are relevant for the present decision:

D2: EP-A-0 106 290

D6: US-A-4 153 739 (cited in the description of the patent in suit)

D11: US-A-4 420 517.

D14-1: JP-A-58-195151 (with English translation).

IV. Oral proceedings took place on 24 January 2005.

The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted or, in the alternative, according to the first auxiliary request filed at the oral proceedings, or

according to the second auxiliary request filed with letter dated 23 December 2004.

The respondent (opponent) did not appear at the oral proceedings, even having been duly summoned, but requested in writing that the appeal be dismissed.

V. Claim 1 of the main request 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."

Claim 1 of the first auxiliary request as filed during the oral proceedings 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, and

a thixotropic partitioning agent within said vessel, said agent being capable of forming a partition between the serum and blood clots after centrifugation."

Claim 1 of the second auxiliary request reads as follows:

"Use of 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, together with a thixotropic partitioning agent

within said vessel, said agent being capable of forming a partition between the serum and blood clots after centrifugation, as a storage vessel for blood serum."

VI. In support of his request the appellant relied on the following submissions.

The container described in D14-1 was designed for blood testing and it was usually made of glass. On the contrary, the container according to the invention was designed for vacuum storing blood for relatively long periods to allow delayed tests and that implied a different design of the container, in particular a different thickness of the walls of the container. Therefore D14-1 did not represent the closest state of the art.

Even if D14-1 would be considered as representing the closest state of the art, the skilled person in the field would not have combined its teaching with the teaching of D11, since D11 did not disclose polyethyleneterephthalate as material for the tube, but exclusively glass (see column 2, line 53).

Furthermore D11 suggested the use of a thixotropic material in a vacuum tube made of glass. Claim 1 of the auxiliary requests however encompassed the presence of a thixotropic material in a vacuum tube made of a special material, in particular of polyethyleneterephthalate. Table 2 of the patent in suit proved the surprising positive effect of the combination of polyethyleneterephthalate with thixotropic material. Such positive effect was also explicitly stated in the patent in suit, paragraph

bridging pages 7 and 8. Since the combination of the thixotropic material with the material of the vacuum tube was essential for the effect of the thixotropic material, a combination of the teaching of D14-1 and D11 could not be regarded as obvious.

Reasons for the Decision

1. The appeal is admissible.
2. *Inventive step*
- 2.1 D14-1, which originates from the same inventor as the present invention, discloses:

A blood-collection tube comprising a tube-shaped vessel (see claim 1 and page 2, lines 4 to 6), said vessel being fabricated from polyethyleneterephthalate (see page 5, lines 6 to 13), 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 (see paragraph bridging pages 4 and 5);

(b) an adsorptive inorganic substance capable of accelerating blood coagulation and selected from glass, silica, kaolin, cerite and bentonite (see page 8, line 15, to page 9, line 9); 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 (see paragraph bridging pages 7 and 8).

The appellant's argument that D14-1 could not be considered as representing the closest state of the art, since it did not disclose a vacuum tube, is not convincing. According to the case law of the boards of appeal, (see 4th edition, English version, I.D.3.2, page 102), in selecting the closest prior art, the first consideration is that it must be directed to the same purpose or effect of the invention and that this prior art was generally that which corresponded to a similar use requiring the minimum of structural and functional modifications. In the present case, D14-1 refers, as does the claimed device, to a vessel for blood tests. Hence it is directed to the same purpose as the invention and it corresponds to a similar use. Furthermore, since the vessel of D14-1 is made of one of the claimed materials and the coating is exactly the same as described in sections (a), (b) and (c) of claim 1 according to all present requests, D14-1 requires a minimum of structural modifications in order to come to the claimed blood-collection tube.

2.2 However, D14-1 does not disclose

- that the vessel is a vacuum tube 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 (see claim 1 of the main requests), and

- that the blood-collection tube comprises a thixotropic partitioning agent within said vessel, said agent being capable of forming a partition between the serum and blood clots after centrifugation (see claim 1 of the first and second auxiliary requests).

2.3 Starting from D14-1, the object to be achieved by the subject-matter of the main request is to be seen in adapting the blood collection tube known from D14-1 to be suitable for being used as a vacuum tube and as a storage vessel for blood serum (see patent in suit, page 3, lines 40 to 45).

Vacuum blood-collection tubes having a vessel which has 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, are well known (see for example D2: page 1, lines 15 to 18; D11: column 2, from line 50; D6: column 3, from line 31). The adaptation of the blood-collection tube according to D14-1 to such a vacuum blood-collection tube was therefore obvious for the skilled person.

The argument that the skilled person would not combine the teaching of D14-1 and D11, since the tube of D11 was made of glass, is not convincing. It is true, as the appellant argues, that in order to provide a vacuum tube made of polyethyleneterephthalate to be used for a long storage blood vessel, the walls of the tube must have an adequate thickness. However, it is to assume

that the skilled person in the field is able to find a suitable thickness of the tube wall, for example on the basis of routine tests, without the exercise of inventive skills.

- 2.4 The additional object to be achieved by the subject-matter of the first auxiliary request has to be seen in providing the possibility to decant the serum (see page 6, lines 15 to 18 of the patent in suit).

However, the provision of an agent to achieve this object is usual in the field of blood-collection tubes. This is even admitted in the patent in suit (see description, page 6, line 15). Furthermore, the provision of such an agent is suggested by D11 (see paragraph bridging columns 2 and 3). Therefore the subject-matter of the first auxiliary request is also obvious.

The appellant's argument that the skilled person would not have considered combining a thixotropic partitioning agent with a tube having the walls of polyethyleneterephthalate, can not be followed, since the appellant could not submit any evidence supporting this statement. It is true that Table 2 of the patent in suit shows that using a thixotropic agent in a tube of polyethyleneterephthalate gives more stable values for LHD and K than using it in a tube of glass (compare the values under the heading "polyethyleneterephthalate tube-shaped vessel" with "control 1" in Table 2). However, since the use of polyethyleneterephthalate for a blood-collection tube is already known from D14-1, and since the patent in suit itself acknowledges that it is normal using a thixotropic agent within blood

test vessels, the person skilled in the field would have arrived at the claimed favourable combination by way of a workshop activity without any inventive skill being involved.

2.5 Second auxiliary request

The second auxiliary request comprises a claim 1 directed to the use of the tube as defined in claim 1 of the first auxiliary request, including the thixotropic partitioning agent. Since this use does not encompass any specific feature additional to the device of claim 1 of the first auxiliary request, the assessment made with respect to the first auxiliary request is also valid for the second auxiliary request.

3. *Conclusions*

From the above considerations, it follows that the subject-matter of claim 1 of all the requests does not involve an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

T. Kriner