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D E C I S I O N
of 19 June 1997

Case Number: T 0756/95 - 3.2.2

Application Number: 87901905.7

Publication Number: 0305364

IPC: A61M 1/00

Language of the proceedings: EN

Title of invention:
Purging system for a blood tubing network

Applicant/Patentee:
Baxter International Inc. (a Delaware corporation)

Opponent:
Fresenius AG

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (confirmed)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0756/95 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 19 June 1997

Appellant: (Opponent)
Fresenius AG
D-61343 Bad Homburg v.d. Höhe (DE)

Representative:
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Respondent: (Proprietor of the patent)
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Representative:
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 8 May 1995 concerning maintenance of European patent No. 0 305 364 in amended form.**

Composition of the Board:

Chairman: H. J. Seidenschwarz
Members: M. G. Noel
J. C. M. De Preter

Summary of Facts and Submissions

I. In consequence of an opposition filed by the appellant against the European patent No. 0 305 364, the opposition division decided in an interlocutory decision dated 8 May 1995 to maintain the European patent in amended form.

II. Independent method and apparatus claims read as follows:

"1. A method for maintaining the sterility until actual usage of at least one tubular blood collection/return needle (12, 14) mounted at the terminal end of a tubing network, said method comprising the step of manufacturing the tubing network as a sterile unit including the needle with the needle removably coupled with a housing (16, 200, 300) with the needle (12, 14) accessing a sterile chamber (102, 208, 302) of the housing (16, 200, 300) such that the needle (12, 14) is in liquid communication with the chamber (102, 208, 302); inserting the tubing network unit into a blood processing apparatus, with the needle coupled in liquid communication with the sterile chamber, pumping a sterile liquid into said chamber (102, 208, 302) through said needle (12, 14) and then allowing at least some of said liquid to exit said chamber (102, 208, 302) and flow back into said network whereby the sterility of the needle (12, 14) is maintained until actual usage and the system is purged of air by the liquid flow, and uncoupling the needle from the housing for use."

"7. Apparatus for use in the method of claim 1, comprising a blood processing system and apparatus, usable for purging air from the blood processing system (10), the apparatus comprising a tubing network which

is manufactured as a sterile unit including a collection needle (12) at one terminal end thereof, a return needle (14) at another terminal end thereof, a housing (16, 200, 300) having a sterile interior chamber (102, 208, 302), and coupling means removably coupling the needles (12, 14) to the housing (16, 200, 300) so that both needles (12, 14) access the same sterile chamber (102, 208, 302) of the housing (16, 200, 300) such that flow communication between said chamber (102, 208, 302) and the needles (12, 14) is established, the tubing network unit being connectable to the blood processing system, with the needles coupled in liquid communication with the sterile chamber, whereby passage of a sterile liquid through the tubing network unit including the chamber (102, 208, 302) to purge air from the network maintains the sterility of the needles (12, 14) until actual usage."

III. The appellant lodged an appeal on 9 June 1995 against the first instance's decision and paid the appeal fee in due time. In its statement of grounds filed on 16 September 1995 and in its subsequent written submissions, the appellant disputed the inventive step of the claimed subject-matter vis-à-vis the state of the art referred to by the opposition division and supplemented by new documents.

The respondent replied to the appellant's contention on 25 March 1996 and filed a main request (with independent claims corresponding to the version above) and an auxiliary request along with additional documents to support its view.

IV. Oral proceedings were held on 19 June 1997, at the beginning of which the respondent withdrew its auxiliary request.

(i) The following documents were referred to during oral proceedings.

(1) EP-A-0 203 513

(2) DE-A-3 442 744

(4) "Extended storage of single-donor platelet concentrate collected by a blood cell separator" by D. H. Buchholtz et. al. Transfusion, vol. 25, No. 6-1985, pages 557-562

(7) "Improvement of the Safety Systems in Cell Separators" by H. J. Neumann et. al., Infusionstherapie 14, suppl. 4-1987, pages 43-51.

(ii) The appellant argued essentially that the subject-matter of the patent in suit differed from the disclosure of document (2) only in that the needles to be inserted in the patient were already included in the tubing network manufactured as a sterile unit. Since, however, the tubing arrangement described in document (1) showed the possibility of providing connector pieces with needles, the claimed subject-matter was suggested by the combination of the disclosures of documents (2) and (1), having regard to the teachings of documents (4) or (7) acknowledging each the use of a blood processing system manufactured as a unit with pre-attached needles integrally connected to the closed system, in accordance with the prescribed medical

regulations and standards, so that no connections needed to be made by the user and the risk of bacterial contamination was avoided.

(iii) The respondent submitted, substantially, that neither document (1) nor document (2),suggested a network that was connected to a blood processing apparatus made as a sterile pre-connected unit ready for priming with the needle in a pre-connected condition in a sterile chamber, so that in accordance with the invention, there was no exposure of the needle to the environment until actual usage. In both documents the connection to accommodate purging was made at the expense of needle sterility and, therefore, they taught directly away from any consideration of preserving needle sterility while purging.

As to documents (4) and (7), they generally referred to disposable closed unit systems possibly including pre-attached needles but without describing any specific embodiment. Since nothing in the prior art suggested a tubing network that tied the dual goals of sterility and purging together by using a needle housed in a sterile chamber, the claimed subject-matter had to be regarded as inventive.

V. 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 and that the patent be maintained as amended.

Reasons for the Decision

1. The appeal is admissible.

2. *Closest prior art and novelty*

2.1 Document (2) relates to a dialysis apparatus to be re-used after cleaning and disinfection operations in order to spare costs. After the dialysis treatment (and disconnection of the apparatus from the patient), the apparatus is cleaned and disinfected by successive flow of flushing and disinfecting fluids through the closed tubing network obtained by connecting terminals 140, 142 with terminals 58, 76, respectively. The tubing network is then filled up with a sterile fluid for keeping it in sterile conditions till the next usage.

A new cycle of flushing and filling of the tubing network is carried out shortly before re-using the apparatus. A short circuit piece 144 is connected between terminals 140, 142 so as to close and isolate the blood processing circuit 114 and the performance and functioning parameters of the dialysis apparatus are monitored. At the same time, purging of the tubing network occurs through a ventilating valve 134. After the purging of the system, the short circuit piece is removed by the user from the terminals 140, 142 and, instead, input and output needles are connected for subsequent insertion in a patient, so that a new dialysis treatment can take place.

While the system disclosed in document (2) allows for purging air by liquid flow through the tubing set and for keeping it sterile until the next use, the object of the known system is not concerned with maintaining needles sterility, since the needles are not integral

with the tubing network and, consequently, they have to be manually attached just before use. For this reason, a sterile chamber for housing the needles and coupling means for easily connecting/disconnecting the needles to and from the enclosing chamber in the sense of the patent in suit are not disclosed in this document.

Consequently, document (2) does not disclose any feature of the method claim 1 in suit and only a few isolated features of the apparatus claim 7. Therefore, document (2) cannot be regarded by the Board as the closest prior art.

2.2 Document (1) represents the state of the art which comes closest to the invention. It describes a medical bag arrangement for use in flushing out a blood treatment apparatus, eg a blood tubing system connected to a dialyser, in order to remove adhering chemicals. As in the patent in suit, the whole system works as a closed system with respect to the surroundings, ie a sterile state is maintained during flushing while the entire air is purged from the tubing system.

In the embodiment according to Figure 1, a blood tubing system 5 including a dialyser 62 is connected to a double-chamber bag arrangement 10 by means of complementary connector pieces 58/26 and 64/38, so that flushing liquid contained in the bag arrangement is circulated through the tubing system while air is expelled towards the second bag collection chamber 14. The flushing liquid recycles back into the first bag chamber 12 whilst the used flushing liquid remains in the second chamber. As soon as only fresh flushing liquid is conducted continuously through the dialyser, fluid circulation is stopped, the connector parts are separated from each other and the connector pieces of the tubing system are provided with needles to be injected into a patient in view of a dialysis

treatment. In this embodiment as in the embodiment disclosed in document (2), the needles are not part of the tubing set and, therefore, they are exposed to contamination during handling.

In the second embodiment according to Figure 2, however, the connector pieces 82/88 of the bag arrangement 70 are provided with pierceable membranes 84/90, respectively, while the corresponding connector pieces 58/64 of the blood tubing system (only illustrated on Figure 1) are provided with needle fittings to enable the membranes to be pierced by the needles. In this case, flushing and purging occur through a closed tubing network including pre-connected needles. However, the needles are not initially sterile and, moreover, they are further exposed to a non-sterile environment when they are (manually) connected to the connector pieces for the membranes to be pierced in order to connect the dialysis equipment with the bag arrangement.

2.3 With respect to the disclosure of document (1), the subject-matter of claims 1 and 7 differs essentially by the following features:

- The tubing network including the needle is manufactured as a sterile unit, ie the needle is integral with the tubing network and maintained sterile, from manufacture until use. In contrast, the tubing network disclosed in document (1) is not placed in a condition ready for priming until after connection of the separate parts. Coupling the bag arrangement to the blood processing apparatus breaches sterility, so that the needles are subjected to additional risk of contamination.

- The needle accesses a sterile chamber in a housing such that the needle is in liquid communication with the sterile chamber.

  In document (1), the needles are directly inserted into the inlet and outlet tubing of the flushing liquid reservoir (bag arrangement) so that a separate sterile chamber for housing the needles is not present is this document.

- Removable coupling means are provided for coupling/uncoupling the needle with the sterile chamber, whereby sterility of the needle is maintained until actual usage.

  Such coupling means cannot exist in document (1), given the absence of any sterile chamber in the sense of the present invention.

Therefore, the subject-matter of independent claims 1 and 7 is novel within the meaning of Article 54(1) EPC.

3. *Inventive step*

3.1 The technical problem underlying the present patent is to provide a system for purging air from a disposable tubing set while maintaining the needle(s) in a sterile environment until actual usage, ie minimizing the time interval in which the needle(s) is exposed to a non-sterile atmosphere.

The solution to this problem is given by the features recited in the main claims, which are distinguished over the closest prior art (cf. point 2.3 above), in particular by the fact that the collection and return needle(s) later to be used for intravenous connection is enclosed in a sterile housing that is also used to facilitate the purging cycle. Since the tubing network

will remain closed during the purge sequence, a continuous flow path of sterile liquid is provided through the tubing and further through the sterile chamber and the needle(s) so as to move otherwise trapped air pockets to any proper discharge point of the tubing network, while maintaining the needle(s) sterile up to use.

It is important to notice here that in order for sterility of a needle to be maintained, the needle must be sterile, initially. Therefore, a sterile unitary network is manufactured including blood processing device, tubing, needle(s) and a housing. The needle is held in a sterile chamber in the housing and sterility is maintained by flow of sterile fluid through both the needle and the chamber.

3.2 The second embodiment referred to in document (1) does not start with sterile needles, so it is clear that the problem of preserving sterility is not considered. Needles are provided on the connector pieces of the blood tubing network with the sole view to piercing the membranes covering the connector pieces of the bag arrangement, otherwise normally sealed with a cap in the unused state. Since, however, bringing together the two-part system in one unit is necessary for priming, the sterility of the needles and of the tubing network cannot be guaranteed when considering all operating steps from the manufacture of the entire blood processing system up to its use.

Thus, even if document (1) provides a solution to the general problem of simultaneously flushing and purging a tubing network before use, this solution is not satisfactory from the standpoint of sterility. The

embodiments disclosed in document (1) differ from the claimed solution as well by the structural features of the apparatus as by the method steps performed by the apparatus for maintaining sterility until actual usage.

None of the cited prior art documents suggests enclosing the collection needles in a sterile chamber forming a part of the disposable tubing network of a blood processing system manufactured initially as a unit. Therefore, even by combining the disclosures of documents (1) and (2) one would not arrive at the claimed subject-matter of the invention. In document (1) as in document (2) the act of purging necessitates, at least once, exposing the needles to the environment at the expense of sacrificing needle sterility. Document (1) like document (2) offers no solution to the problem addressed in the patent, much less the solution defined in the main claims.

Should the skilled person have decided, nevertheless, to cover the connectors provided with needles, according to the alternative embodiment described in document (1), with the short circuit piece disclosed in document (2), regarded then as a common enclosure, one still would not arrive at the claimed subject-matter since, by removing the bag arrangement of flushing fluid and replacing it by a short circuit piece, there would not be any more possibility of supplying flushing fluid for purging the tubing set. Also, the skilled person had no reason without the benefit of hindsight to provide the terminals 140, 142 of the tubing described in document (2) with needles and subsequently to close the flow path with the short circuit piece 144 since, as already demonstrated, maintaining the needles in a sterile condition is not a problem which is addressed in this document. Moreover, the short circuit piece is not provided with membranes to be pierced.

3.3 Document (4) acknowledges performing blood component processing by means of a disposable closed-system apheresis kit (Fenwal system) in which the needles are pre-attached, ie supplied integrally connected to the apheresis kit, so that no connections need to be made by the user and the possibility of bacterial contamination inherent in the physical connection is avoided.

However, while document (4) discloses the general concept of pre-attaching needles to a tubing set, possibly manufactured initially as a closed and sterile system, this document contains no concrete or more detailed information as to how the closed system should be realized. In particular, no suggestion is made of enclosing the needles in a sterile chamber removably provided with coupling means, so that a sterile liquid is allowed to pass through the tubing network including said chamber in order to purge air by the liquid flow while maintaining sterility until actual use. The distinguishing features referred to in point 2.3 above are, therefore, not disclosed nor suggested by document (4), either. Thus, even if taken in combination with the disclosure of document (1) or document (2), the general concept described in document (4) would still not arrive at a priming system as defined in the claimed subject-matter. To reach identical features, the skilled person would be required to develop his own design modifications, which represent the inventive contribution of the claimed solution.

3.4 Document (7) discloses nothing more than document (4). It relates to the improvement of safety systems for the separation of blood and generally describes the concept of using a unique and disposable closed seal-less tubing system, ie completely closed from inside and outside in a sterile manner, with a view to reducing

the possibility of contamination in accordance with the standards and rules for the proper manufacture of medical products. No mention is made of needles, let alone of needles integral with the tubing set.

Again, as rightly submitted by the respondent, the claimed invention is not directed simply to a closed system possibly provided with pre-connected needles, but to a complete network connected to a blood processing apparatus as a sterile pre-connected unit, with at least a needle housed in a sterile chamber that is also used for purging, such that sterile liquid pumped through the chamber not only purges the tubing network but also maintains the sterility of the needle. This concept and associated apparatus are in no way derivable from the prior art documents.

3.5 For all the foregoing reasons, the Board is satisfied that the subject-matter of the method claim 1 and the apparatus claim 7 for performing the method cannot be derived in an obvious manner from the state of the art. Consequently, the provision of Article 56 EPC are met and the European patent can stand as it is.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

N. Maslin

The Chairman:

H. Seidenschwarz