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D E C I S I O N
of 10 September 1998

Case Number: T 0232/96 - 3.2.2

Application Number: 89301138.7

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Language of the proceedings: EN

Title of invention:
Catheter valve assembly

Patentee:
Becton, Dickinson and Company

Opponent:
B. Braun Celsa

Headword:
-

Relevant legal provisions:
EPC Art. 54(1), 56, 83, 84, 102(3)

Keyword:
"Disclosure of the invention (sufficient)"
"Novelty and inventive step (confirmed)"

Decisions cited:
T 0301/87

Catchword:
-

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D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 10 September 1998

Appellant: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 8 January 1996 concerning maintenance of European patent No. 0 328 332 in amended form.**

Composition of the Board:

Chairman: W. D. Weiß
Members: M. G. Noel
C. Holtz

Summary of Facts and Submissions

I. Upon opposition by the appellant against the European patent No. 0 328 332, the opposition division decided in an interlocutory decision dated 8 January 1996 to maintain the patent in amended form.

II. Claim 1 under consideration in the decision under appeal reads as follows:

"A catheter assembly (10) for controlling positively the passage of fluids therethrough to and/or from a blood flow passage in which it is inserted, comprising an elongate catheter tubular body (12); characterised by

(a) said catheter tubular body (12) having an open proximal end and an open distal end (25);

(b) one or more lumens (11) extending in said catheter tubular body (12) from said open proximal end to said open distal end;

(c) a substantially tubular sheath (14) positioned over the said open distal end (25) of said tubular body, and extending from said open distal and to a point spaced from said open distal end;

(d) a substantial portion of a surface of said sheath engaging a surface of said catheter tubular body;

(e) said sheath (14) engaging said catheter tubular body in a non-slip engagement;

(f) a slit valve (16) positioned in said sheath and which responds to pressure differentials on either side of the valve for passage of fluid to or from said fluid flow passage; and

(g) said slit valve (16) being positioned in the wall of said sheath in an area not covering the surface of said catheter tubular body."

III. The appellant lodged an appeal on 6 March 1996 against the first instance's decision and paid the appeal fee in due course. In its statement of grounds filed on 7 May 1996, the appellant disputed the patentability of the subject-matter of claim 1 vis-à-vis the state of the art represented by documents:

(0) US-A-4 701 166,

(1) GB-A-727 959, and

(4) US-A-3 525 357.

IV. The appellant argued as follows:

- The feature that the catheter positively controls the passage of fluids to and from a blood flow passage did not involve the catheter itself, but the environment in which it was inserted. If, as the opposition division indicated, this meant that the catheter still had to have certain characterisitics, these had to be described in the patent. But the essential structural features for making such a catheter, in particular for performing the two-way valve function of the slit valve were missing in claim 1. Therefore, the novelty and inventiveness of the invention could not be assessed.

- Document (1) disclosed all the features recited in claim 1, with the exception of the catheter being inserted in a blood flow passage and of the flow of fluid being controlled in two opposite directions. Since, however, the oesophageal tube disclosed in document (1) might also be used as a catheter assembly to be inserted in a blood flow passage, the subject-matter of claim 1 was not new with respect to the teaching of this prior art document.

- As to the issue of inventive step, either of documents (0) or (4) could be regarded as closest prior art. Document (0) disclosed a two-way valved catheter, but not rigid enough for the fluid to flow equally easy in both directions. Since document (1) stated that the catheter tube might be strong enough not to collapse during its use, the subject-matter of claim 1 was suggested by the combination of documents (0) and (1). Further, document (4) disclosed a plurality of slit valves functioning one-way, which could be easily modified to function in the same manner as the two-way valves exemplified in document (0). The required structural modifications would not exceed the normal competence of a person skilled in the art. Therefore, the subject-matter of claim 1 was obvious also with regard to the combination of documents (0) and (4).

V. The respondent (patent proprietor) replied to the appellant's contentions by letter dated 5 August 1996.

VI. 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. *Disclosure of the invention and clarity*

The Board understands the appellant's objections as to the catheter to be an objection under Article 100(b) EPC. However, the objection that certain characteristics of the catheter should have been described in the patent is not a subject for the appeal. The appellant withdrew its ground of opposition under Article 100(b) EPC before the opposition division. No amendment of the claims or the description has been made since then.

The requirements of Article 84 EPC do not belong to the grounds for opposition as enumerated in Article 100 EPC. Although amendments must be examined also with clarity in mind, Article 102(3) EPC does not allow fresh objections to be based on Article 84 EPC, unless they arise out of the amendmends made (see e.g. T 301/87, OJ EPO, 1990, 335). Since no amendments have been made, no clarity issue arises in the present appeal.

3. *Closest prior art*

Document (0) is considered as the state of the art coming closest to the invention since it was already referred to in the background part of the application as filed and it discloses a catheter assembly for positively controlling the passage of fluid therethrough to and/or from a blood flow passage in which the catheter is inserted, in accordance with the pre-characterising portion of claim 1.

More specifically, the two-way valve catheter described in document (0) comprises a flexible (rubber) tubular body 12 closed at its proximal end 18 by a rounded tip portion. A two-way valve is formed integrally with the catheter tube by cutting a slit through a generating line of the tubular wall. Due to the flexible nature of the tube, a removable internal pushing rod 16 is used to insert the catheter at the required location into a blood vessel.

With respect to the embodiment described in document (0), the subject-matter of claim 1 is distinguished by the following features:

- the catheter tubular body is open at both ends (feature (a))

- the open end of the tube which is to be inserted (distal end) is covered by a tubular sheath engaging a surface of the tubular body in a non-slip engagement (features (c) to (e))

- the slit valve is realized in the sheath and positioned in an area not covering the surface of the tubular body (features (f) and (g)).

4. *Novelty*

From the foregoing, it results that the subject-matter of claim 1 is novel over the closest prior art. However, novelty was disputed by the appellant with respect to the teaching of document (1).

Document (1) discloses an oesophageal tube for use with an animal drench gun, comprising a rigid portion 10 and a flexible tube portion 20 (rubber) provided at its end with a soft discharge tip or nozzle 24. In the

embodiment according to Figure 1, the nozzle has a slit or holed membrane 26 for providing a passage to the liquid forced through the membrane by the drench gun. In addition, the rigid portion includes a one-way valve 18 to prevent return flow of liquid. In Figure 2, the nozzle is provided with a central fluid discharge orifice 36, and a star-shaped non-return valve member 37 is interposed between the nozzle and the end of the flexible tube. In both cases, the liquid is forced away by fluid pressure through the valve member 26 or 37 when the drench gun is operated, so that the liquid is entitled to flow only one way. Since the valves are not designed to respond to pressure differentials on either side, the oesophageal tube described in document (1) is neither used for nor capable of controlling the passage of fluid coming from the body passage in which the tube is inserted.

With respect to document (1) the subject-matter of claim 1 differs, therefore, by the features contained in its pre-characterising portion and by the characterising feature (f). Consequently, the subject-matter of claim 1 is also novel over the disclosure of document (1), within the meaning of Article 54(1) EPC.

5. *Inventive step*

5.1 The two-way valve catheter disclosed in document (0) suffers from a number of drawbacks as mentioned in the background part of the present patent (cf. column 2, lines 39 to 55). In particular, although the slit-type valve may operate in two directions, it actually works well only where outward flow is desirable. Moreover, the weakened tip of the catheter is prone to bending due to patient movement or to collapse during aspiration, which can cause inadvertent opening of the valve by deformation of the tip of the tube.

The problem underlying the present invention was, therefore, to find a compromise between optimizing the valve performance so that it is responsive to fluid pressure differentials, and providing a valve that stays closed when required and that is strong enough not to collapse during aspiration (cf. column 2, line 55 to column 3, line 2).

The solution to this problem is given by the combination of features as claimed, in particular by the fact that the open distal end of the tubular body is covered with a separate flexible tubular sheath provided with a two-way valve. Thus, not only is the tubular body of the catheter closed by the sheath overlapping it, but also the dual wall structure formed by the sheath engaging a surface of the tubular body contributes to improving the structural integrity and the overall stability of the catheter to be inserted, thus avoiding the above-mentioned deficiencies. In the Board's view, this is the sense in which the expression "more body" used at several occasions in the patent in suit, has to be understood (cf. column 3, lines 48 to 53; column 4, lines 7 to 25 and column 7, lines 46 to 50).

5.2 The skilled person would not have considered document (1) since, as already mentioned, the delivery tube described therein is not suitable for insertion into a blood flow passage and is designed to provide a fluid flow in one direction only. In the absence of any additional information about the structure and properties of the slit valve, it is highly doubtful whether said valve would be able to function satisfactorily also in the reverse flow direction, i.e. from the human body passage to the catheter tube and so could be used as a bidirectional catheter for controlling a flow of blood in both directions.

Should the skilled person nevertheless have decided to combine the teachings of documents (0) and (1), he would not have arrived at the claimed subject-matter. To this end, the skilled person would at first have replaced the closed end of the catheter described in document (0) by the slit discharge nozzle disclosed in document (1). But since in both cases the tubings are made of flexible material, a pushing member such as 16 in document (0) would still have been necessary for facilitating insertion of the catheter through a blood vessel. However, with a slit valve positioned at the tip end of the catheter tube, the use of such a pushing member turns out to be totally excluded. Therefore, a combination of these documents is unlikely.

Furthermore, in document (1), the end of the flexible tube portion is reduced in diameter, as shown at 22, such that by fitting the discharge nozzle on the reduced portion of the tube, the outer diameter of the flexible assembly as a whole remains constant. However, by reducing the diameter, the structural integrity of the delivery tube has been altered, which alteration the invention precisely aims to avoid (cf. patent, column 4, lines 7 to 11). As a matter of fact, in the present patent, the thickness of the catheter wall remains unchanged, whereas the covering sheath forms a dual wall structure, thus providing the above mentioned advantageous effects ("more body"). Such effects are implicitly contained in feature (c) of claim 1, when interpreted by the description. Therefore, this teaching in the patent also goes against the conclusion that a combination of the teachings of documents (0) and (1) would lead the skilled person to the subject-matter of claim 1.

5.3 Document (4) is totally irrelevant since it does not refer to a catheter assembly. It discloses a pump valve apparatus for cyclically forcing a liquid such as blood through a pair of lines provided with valves. Four slit valves 25 are positioned within a pair of flexible lines 14, 16 to be squeezed between respective pairs of plates 11, 13 and 12, 15. When, for example, the pressure plate 13 moves towards plate 11, the flexible line 14 is squeezed, whereby the liquid under pressure in this line forces one valve to open to permit flow of fluid in one direction (arrow 31) while the opposite valve in the same line is forced to close (cf. column 3, lines 44 to 49).

Therefore, each elementary valve such as that illustrated in Figure 2 operates in only one direction and would be inoperative in the present invention. Consequently, also by combining the teachings of documents (0) and (4), the skilled person would still not have arrived at the subject-matter of claim 1.

5.4 Since the skilled person was unable to find in any of the cited documents a suggestion or an incitement to modify the known valve arrangements in the way as claimed, the subject-matter of claim 1 cannot be derived in an obvious manner from the state of the art, as required by Article 56 EPC. The dependent claims 2 to 10 stand with the allowable main claim.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin W. D. Weiß