

Internal distribution code:

- (A) Publication in OJ
(B) To Chairmen and Members
(C) To Chairmen

D E C I S I O N
of 29 February 2000

Case Number: T 0198/97 - 3.2.2

Application Number: 84303006.5

Publication Number: 0125844

IPC: A61M 25/00

Language of the proceedings: EN

Title of invention:

Valved two-way catheter

Patentee:

BARD ACCESS SYSTEMS, INC.

Opponent:

Cook Pacemaker Corporation
B. Braun Celsa

Headword:

-

Relevant legal provisions:

EPC Art. 54, 56, 100(b)

Keyword:

"Novelty (yes)"
"Inventive step (yes)"
"Feasibility (yes)"

Decisions cited:

-

Catchword:

-



Case Number: T 0198/97 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 29 February 2000

Appellant: BARD ACCESS SYSTEMS, INC.
(Proprietor of the patent) 5425 West Amelia Earhart Drive
Salt Lake City
Utah 84116 (US)

Representative: Marsh, Roy David
Hoffmann Eitle
Patent- und Rechtsanwälte
Postfach 81 04 20
D-81904 München (DE)

Respondents: Cook Pacemaker Corporation
(Opponent I) Route 66, River Road
P.O. Box 529
Leechburg Pennsylvania 15656 (US)

Representative: Behrens, Dieter, Dr.-Ing.
Wuesthoff & Weusthoff
Patent- und Rechtsanwälte
Schweigerstrasse 2
D-81541 München (DE)

(Opponent II) B. Braun Celsa
30, Avenue des Temps Modernes
F-86360 Chasseneuil du Poitou (FR)

Representative: Lerner, François
Lerner & Associés
5, rue Jules Lefèbvre
F-75009 Paris (FR)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 20 December 1996
revoking European patent No. 0 125 844 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: W. D. Weiß
Members: S. S. Chowdhury
J. C. M. De Preter

Summary of Facts and Submissions

I. The Appellant (Proprietor of the patent) lodged an appeal against the decision of the Opposition Division to revoke the patent No. 0 125 844. The decision was dispatched on 20 December 1996.

The appeal and the fee for appeal were received on 20 February 1997. The statement setting out the grounds of appeal was received on 30 April 1997.

Opposition was filed against the whole patent and based on Article 100(a) EPC (lack of novelty and inventive step) and on Article 100(b) (insufficient disclosure).

The Opposition Division had decided that the grounds for opposition specified in Article 100(a) EPC prejudiced the maintenance of the patent because the subject-matter of claim 1 as granted lacked novelty in view of document D7. The following prior art documents among those regarded as relevant by the Opposition Division have been taken into account as relevant documents during the appeal proceedings:

D1: GB-A-1 417 013

D4: US-A-4 327 722

D7: US-A-3 888 249

II. In response to a communication of the Board, the Appellant filed by letter dated 28 January 2000 amended claims according to auxiliary requests A, A1, B, B1 and B2.

Oral proceedings took place on 29 February 2000, at which only the appellant was represented. Both the respondents (opponents) had stated their intention of not appearing at the oral proceedings.

III. At the end of the oral proceedings the appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or that the patent be maintained in amended form according to one of the auxiliary requests as submitted by letter dated 28 January 2000.

Respondent I (Cook Pacemaker Corporation) requested by letter of 11 March 1997 that the appeal be dismissed, but filed no substantial arguments.

Respondent II (B. Brown Celsa) did not file any substantial request at the appeal stage.

The independent claims 1 and 16 of the main request read as follows:

claim 1:

"A valved catheter suitable for temporary or permanent implantation in the vascular system of a patient, said catheter comprising a catheter tube (12) formed from a resilient, flexible material, said catheter tube having a closed proximal end (18) and adjacent thereto a slit (24) through the catheter wall, the slit (24) comprising a pair of opposed faces in complete contact under normal physiological pressures, whereby when predetermined positive or negative pressure gradients exist across the catheter wall the catheter wall

contiguous the slit (24) deforms and causes the opposed faces of said slit (24) to withdraw from one another to form a temporary orifice in the catheter wall through which fluid may be infused into the body of the patient when the said pretermined pressure gradient is positive, or withdrawn when the predetermined pressure gradient is negative, whereby the slit forms a two-way valve for the passage of fluid into or out of the catheter, said catheter being characterised by the catheter tube (12) having a hardness of less than 100 durometer and being further characterised by the material of the catheter wall being more pliable in the vicinity of the slit (24)."

claim 16:

"A method for manufacturing a catheter comprising the steps:

(a) fabricating a tube (12) of a resilient, flexible material having a hardness of less than 100 durometer, said tube having a closed proximal end (18);

(b) forming a slit (24) through a wall of the tube (12) at a location adjacent the proximal end (18) of the tube (12), said slit (24) comprising a pair of opposed faces in complete contact under normal physiological pressures; and

(c) making the wall more pliable in the vicinity of the slit (24), thereby to create in the vicinity of the slit (24) a region more deformable than other regions of the wall by pressure differentials applies thereacross, said region permitting the wall in the

vicinity of the slit (24) to open outwardly or inwardly, and accommodate fluid flow through the said slit (24) from or into the tube (12), respectively, when positive or negative pressure differentials, respectively, exist across the wall of the the tube (12)."

IV. The Appellant essentially argued as follows:

The decision of the opposition division was flawed in so far as it found D7 to anticipate the subject-matter of claim 1, despite the fact that this document explicitly teaches a one-way valve. Moreover, the opposition division had made unwarranted assumptions regarding the nature of the valve of D7, particularly in view of the empirical evidence submitted at the appeal stage.

The patent proprietor disclosed for the first instance anywhere a catheter valve that is both fully functional and accomplished with elegant simplicity of structure.

Reasons for the Decision

1. The appeal is admissible.
2. *The main request*

As regards the patent as granted (main request), the only points at issue in the appeal proceedings are novelty and inventive step (Article 100(a) EPC) of the claimed subject-matter, and insufficiency of the disclosure (Article 100(b) EPC).

3. *Novelty (main request)*

The Board ascertained during the examination of the cited prior art documents that none of them discloses a catheter with all the features stated either in claim 1 or in claim 16 of the main request. In particular the Board finds the claimed subject-matter to be novel over the disclosure of document D7 since this does not disclose a two-way valve.

The entire tenor of the document D7 is that retrograde blood flow is to be avoided. The document describes catheters for intra-arterial use over prolonged periods, during which there is a danger of blood clotting and blocking the catheter. It discloses the use of slits at the distal end of the catheter, that open to allow medication to enter the blood flow from inside the catheter if positive pressure is applied, and close if the positive pressure is withdrawn, to inhibit retrograde flow of blood into the catheter and thereby prevent blockage of the catheter (column 1, Summary of the invention). This property is also mentioned in the description of the specific embodiment, in column 2, lines 57 to 63. The fact that this also features in claim 1 of this patent is an indication that prevention of retrograde fluid flow is an essential property of the D7 catheter.

Not only is the clear teaching of document D7 that it relates to a catheter with a one-way valve, but the Appellant has also plausibly demonstrated that, under realistic operating conditions, the valve of the catheter of D7 cannot operate in both directions. In this respect the Appellant has filed an affidavit of

Josh Tolkoﬀ in the course of litigation in the USA and submitted a video recording of a demonstration, done with a Spencer catheter (D7) and a Groshong catheter (the present patent) under conditions simulating pressures in a cardiovascular system, i.e. relatively low pressures. The pressure within a human vein is about 20 mm Hg and about 100 mm Hg in an artery. In practice such pressures are generated by syringes. That large pressure differentials are to be avoided in order to minimise damage to free-floating cells is also indicated at column 3, lines 21 to 46 of the patent.

The demonstration clearly shows the contrasting one-way operation of the Spencer catheter and the two-way operation of the Groshong catheter. Under the same conditions the Groshong catheter could be made to infuse and aspirate, whereas the Spencer catheter could be made to infuse but not to aspirate.

Therefore, the Board is satisfied that the D7 catheter is a one-way catheter as stated in this document, and this document does not anticipate the catheter of claim 1, accordingly.

None of the other cited documents discloses the subject-matter of claims 1 or 16 of the main request. In particular, these documents do not disclose a catheter for vascular implantation, which has a slit valve, wherein the material of the catheter wall is more pliable in the vicinity of the slit.

The subject-matter of these claims is, therefore, to be considered as novel within the meaning of Article 54 EPC.

4. *Inventive step*

4.1 Closest prior art

The opposed patent is directed to catheters suitable for temporary or permanent implantation in the vascular system of a patient. Such catheters are of soft flexible material that require the use of a stiffening stylet for insertion through the often tortuous blood vessels. Accordingly, claim 1 relates to "A valved catheter suitable for temporary or permanent implantation in the vascular system of a patient", and has as a feature that the catheter tube has a durometer hardness less than 100, and claim 16 relates to "A method of manufacturing a catheter comprising the steps of (a) fabricating a tube of a resilient, flexible material having a hardness of less than 100 durometer".

The closest prior art to the catheter according to claims 1 and 16 must, therefore, also be a catheter suitable for temporary or permanent implantation in the vascular system of a patient. The Board is of the opinion of that document D7 discloses the prior art closest to the catheter of claim 1 of the main request, since this document shows such a catheter having all the features of claim 1 except for the slit affording a two-way flow of fluid, as set out above.

4.2 Technical problem to be solved

The above difference between the catheter of claim 1 of the opposed patent and that of D7 enables the problem to be defined as: providing a catheter suitable for temporary or permanent implantation in the vascular

system of a patient and permitting fluid flow from or into the catheter tube, respectively, when positive or negative pressure differentials, respectively, exist in the catheter. The problem is formulated in the opposed patent in column 2, lines 3 to 13.

4.3 The solution

The solution employed in the opposed patent and defined in independent claims 1 and 16 is the to make the wall of the catheter more pliable in the vicinity of the slit, thereby to create in the vicinity of the slit a region more deformable than other regions of the wall by pressure differentials applies thereacross.

That the catheter of the opposed patent performs the required function has been amply demonstrated by the affidavit and video recording of Josh Tolhoff.

4.4 Inventive step of the catheter according to claim 1 (main request)

As the Appellant pointed out at the oral proceedings, it is known to provide a catheter with a valve affording two-way fluid flow in the context of an epidural catheter, for instance, as exemplified by D1, but not in the context of a vascular catheter. In fact there is no prior art indicating that it would be useful or possible to provide a valve affording two-way fluid flow in a catheter for implantation in the vascular system of a patient. In view of the prior art the present inventor was the first to realise the potential advantages of a two-way valved catheter, as set out in the patent in column 10, lines 7 to 13.

Therefore, the definition of the problem itself is indicative of inventive activity.

Nor is the solution, as defined in the independent apparatus claim 1 or method claim 16, suggested in the prior art. In particular, neither the prior art discussed in the appeal procedure nor the remaining available prior art documents suggest making a catheter wall more pliable in the vicinity of a slit, thereby to create in the vicinity of the slit a region more deformable than other regions of the wall by pressure differentials applied thereacross, for the purpose of providing a two-way fluid flow function.

During the opposition procedure the opponents suggested that a combination of D7 and D1 would render the claimed subject-matter lacking in inventive step. The Board cannot follow this argument since this combination is not motivated by any teaching of the prior art. Nor is the combination logical, given that vascular catheters are in a different category to epidural catheters, as stated above, and that D7 expressly teaches to avoid retrograde fluid flow whereas D1 describes a catheter with two-way fluid flow.

Document D1 describes an epidural catheter made of a thermoplastics material, adjacent the distal closed end of which are formed slits that are both axially and radially offset so as to preserve the catheter's rigidity. The slits are normally closed but will open upon application of a positive or negative pressure to allow fluid flow in both directions.

Document D7 describes a vascular catheter with distal slits but, while the catheter of D7 may be said to have a wall more pliable in the vicinity of the slits, thereby to create in the vicinity of the slit a region more deformable than other regions of the wall, this is for the purpose of preventing retrograde fluid flow, not to promote two-way flow.

Therefore, a combination of the teachings of the documents D1 and D7, even if the combination were to be suggested in the prior art, would not yield the catheter of claim 1 of the presently opposed patent.

Document D4 describes a vascular catheter of the Groshong type, having an indwelling slit acting as a one-way valve.

The subject-matter of claims 1 and 16 therefore involves an inventive step within the meaning of Article 56 EPC.

5. *Sufficiency of disclosure*

During the opposition procedure respondent II argued that claim 1 and the description do not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art since claim 1 does not specify which Durometer scale is being referred to, and it is not clear what is meant by "more pliable" in claim 1.

The Board is satisfied that the patent implicitly refers to the Durometer A scale since for the person skilled in the art it is general knowledge that this is

the scale appropriate for soft rubber, which is the material of the present catheter. The Board sees no reason to depart from the opinion of the opposition division in this respect, given during the oral proceedings before the division, and set out in the minutes dated 20 December 1996.

As regards the reference at the end of claim 1 to the catheter wall being more pliable in the vicinity of the slit, the Board sees no problem here since this is a clear teaching that the catheter wall in the vicinity of the slit is more pliable than the remainder of the catheter wall.

Therefore, the patent is free from objection under Article 100(b) EPC.

6. Since, in view of the above, the grounds of opposition raised by the Respondents do not prejudice the maintenance of the patent unamended, the patent in suit can be maintained on the basis of the Appellant's main request.
7. Therefore, there is no need to examine the Appellant's auxiliary requests.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained as granted.

The Registrar:

The Chairman:

S. Fabiani

W. D. Weiß