

Internal distribution code:

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

D E C I S I O N
of 23 December 2003

Case Number: T 0230/00 - 3.2.2

Application Number: 94103085.0

Publication Number: 0612535

IPC: A61M 5/142

Language of the proceedings: EN

Title of invention:
Implantable infusion apparatus

Patentee:
Therex Limited Partnership

Opponent:
Tricumed Medizintechnik GmbH
Medtronic, Inc.

Headword:
-

Relevant legal provisions:
EPC Art. 52(1), 54, 56, 84

Keyword:
"Lack of support (main request), first auxiliary request:
clarity (yes), inventive step (yes)"

Decisions cited:
-

Catchword:
-



Case Number: T 0230/00 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 23 December 2003

Appellant:
(Opponent I)

Tricumed
Medizintechnik GmbH
Röntgenstr. 7a
D-24143 Kiel (DE)

Representative:

Schäfer, Horst, Dr.
Schweiger & Partner
Patent- und Rechtsanwälte
Karl-Theodor-Strasse 69
D-80803 München (DE)

Respondent:
(Proprietor of the patent)

Therex Limited Partnership
1600 Providence Highway
Walpole, MA 02081 (US)

Representative:

Meissner, Bolte & Partner
Anwaltssozietät GbR
Postfach 86 06 24
D-81633 München (DE)

(Opponent II)
(withdrawn)

Medtronic, Inc.
700 Central Ave., NE.
Minneapolis, Minn, 55432 (US)

Representative:

Goddar, Heinz J., Dr.
FORRESTER & BOEHMERT
Franz-Joseph-Strasse 38
D-80801 München (DE)

Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted
23 December 1999 concerning maintenance of
European patent No. 0612535 in amended form.**

Composition of the Board:

Chairman: W. D. Weiß
Members: S. S. Chowdhury
U. J. Tronser

Summary of Facts and Submissions

I. The appellant (opponent I, Tricumed Medizintechnik GmbH) lodged an appeal against the decision of the opposition division to maintain European patent No. 0 612 535 in amended form. The decision was dispatched on 23 December 1999.

The appeal, the fee for the appeal, and the statement setting out the grounds of appeal were received on 23 February 2000.

Two oppositions were filed against the whole patent and based on Article 100(a) EPC (lack of novelty and inventive step) and Article 100(c) EPC (the opposed patent contained subject-matter extending beyond the content of the application as filed). One of the opponents (Medtronic Inc.), who was initially a party to the proceedings as of right, withdrew its opposition by letter of 10 April 2001 and since then has not been a party to the proceedings.

The opposition division decided that the patent complied with the requirements of Article 76(1) EPC and that, having regard to the documents cited and the evidence provided, the amended claims submitted during the opposition procedure met all the requirements of the EPC, in particular those of Article 52(1) EPC and Article 100(c) EPC.

The following documents and evidence were relied upon in the appeal procedure:

D1: US-A-3 951 147

D6: US-A-3 731 681

E2: Medtronic Drawings "Exhibit 1"

E3: Medtronic Drawings "Exhibit 2"

E4: Medtronic Drawings "Exhibit 3"

E5: Medtronic Drawings "Exhibit 4"

E2 to E5 is a set of technical drawings of the Medtronic series 86XX implantable fusion apparatus marketed under the name "SynchroMed" and were appended to a Declaration of Kenneth T. Heruth of 14 May 1999 (E7). The respondent acknowledged these as prior publications.

E15: The cut-open Syncromed pump VZ1002183R, purporting to be the actual device depicted by drawings E2 to E5, was supplied by the appellant but the respondent did not accept that this was the actual device represented by the drawings. Therefore, although not formally in the appeal procedure as a prior art device, it was merely referred to in order to clarify certain features of the drawings.

II. Oral proceedings took place on 23 December 2003, at the end of which the following requests forming the basis of the decision were put forward:

The appellant requested that the decision under appeal be set aside and that European patent No. 0 612 535 be revoked.

The respondent (patent proprietor, Therex Ltd. Partnership, USA) requested that the appeal be dismissed or that the patent be maintained in amended form on the basis of claims 1 to 6 as submitted at the oral proceedings and named "1st Auxiliary", description and Figures as granted.

III. Independent claim 1 of the main request reads as follows:

"Implantable infusion apparatus including: a rigid manifold (12) having opposite first and second surfaces and a periphery; a collapsible fluid-tight infusate chamber (36) having a closed end (36a) and an open end (36b); means (38,39,44) for mounting the chamber open end (36b) in a fluid-tight manner to the manifold first surface, said mounting means (38,39,44) comprising an annular body (38) with one edge portion of said body (38) being connected by a first fluid tight connection (39) to the open end (36b) of the infusate chamber (36); a self-sealing inlet port (134,136) in the manifold (12), said inlet port (134,136) being accessible from the manifold second surface; a fluid conduit (132,126) extending between the inlet port (136) and the interior of the chamber (36); a fluid outlet conduit (58,76,82,84,88,94,96,110) communicating between the manifold first surface inside the chamber (36) and the manifold periphery; and a circular groove (42) with radially inner and outer walls is present in the manifold first surface; characterized in that said mounting means (38,39,44) have a peripheral flange and are seated in the groove (42); the other edge portion of the body is connected by a second fluid tight

connection (44) to a wall of the groove (42) and the open end of the chamber (36) is seated in the groove, and a central promontory or mesa (18) is positioned at said second surface of the manifold (12), said mesa (18) having a central axis perpendicular to said second surface, wherein the inlet port is located in the mesa."

Independent claim 1 of the auxiliary request reads as follows:

"Implantable infusion apparatus including: a rigid manifold (12) having opposite first and second surfaces and a periphery; an upper smoothly contoured annular shell (14) and a lower smoothly contoured cup-like shell (16) which are secured to the manifold to form a housing; a collapsible fluid-tight infusate chamber (36) having a closed end (36a), an open end (36b), and convolutions forming a bellows; means (38,39,44) for mounting the chamber open end (36b) in a fluid-tight manner to the manifold first surface, said mounting means (38,39,44) comprising a bracket-shaped annular body (38) with the inner edge portion of said body (38) being connected by a first fluid tight connection (39) to the open end (36b) of the infusate chamber (36); a self-sealing inlet port (134,136) in the manifold (12), said inlet port (134,136) being accessible from the manifold second surface; a fluid conduit (132,126) extending between the inlet port (136) and the interior of the chamber (36); a fluid outlet conduit (58,76,82,84,88,94,96,110) communicating between the manifold first surface inside the chamber (36) and the manifold periphery; and a circular groove (42) with radially inner and outer walls is present in the

manifold first surface, wherein said mounting means (38,39,44) have a peripheral flange (38a) and are seated in the groove (42); the other edge portion of the body is connected by a second fluid tight connection (44) to the outer wall of the groove (42) and the open end of the chamber (36) is seated in the groove, wherein the groove (42) is deep enough so that when the chamber (36) is fully collapsed, its convolutions nest in the groove to a degree that positions the closed end (36a) above the lower edge of the flange (38a) of the body (38), and a central mesa (18) is positioned at said second surface of the manifold (12) and a corresponding promontory is provided in the upper annular shell (14), said mesa (18) having a central axis perpendicular to said second surface, wherein the inlet port is located in the mesa."

Claims 2 to are 6 dependent on claim 1.

IV. The appellant argued as follows:

It was not clear which technical problem was solved by the features of claim 1 of the main request.

The closest prior art was the set of drawings E2 to E5. If it were apparent to the person skilled in the art that a problem arose in welding the bellows to the manifold, then the solution to this problem was not only obvious, it was compulsory, the outer edge of the groove must necessarily be made higher than the inner edge of the groove so as to accommodate the bellows during welding and hence protect them. This solution, therefore, was not inventive.

V. The respondent argued as follows:

Claim 1 of the main request was clear in its own right since it met the condition that it was adequately distinguished from the prior art and enabled the invention to be carried out. It was not necessary to include further possible features in the claim beyond those necessary to clearly distinguish the invention.

In E2 to E5 it was impossible for the bellows to nest within the groove. This feature of claim 1 of the first auxiliary request enabled the stated problem to be solved, which problem and the solution were not disclosed in the prior art.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. Since claim 1 has been amended after grant, it must, according to Articles 111(1) and 102(3) EPC, meet all the requirements of the EPC, including those of Article 84 EPC, that the claim must be clear and supported by the description, and Article 52(1) EPC, that the claimed subject-matter be novel and involve an inventive step.

The examination as to inventive step involves the well known problem and solution approach, which entails an analysis of the technical problem and solution

underlying the alleged invention. A claim is considered to involve an inventive step if the features thereof solve a technical problem in a non-obvious manner. A pre-requisite for this is that the claim must include all those features which are essential for solving the problem. If a claim purports to solve a problem but does not include all the necessary features for this, then it is not properly supported by the description and objectionable under Article 84 EPC.

The characterising part of claim 1 defines two sets of features which relate, respectively, to two different technical problems. The first set of features includes the mounting means having a peripheral flange and seated in the groove and another edge portion connected by a second fluid tight connection to a wall of the groove, with the open end of the chamber being seated in the groove. These features relate to the problem of ease and safety of manufacture, as set out in column 8, lines 23 to 37 of the patent in suit.

However, the features defined in claim 1 are not sufficient for solving this problem. An essential configuration is that the groove is deep enough so that when the capsule is fully collapsed, its convolutions nest in the groove to a degree that positions the bellows end wall above the lower edge of the bracket flange. This clearance allows a weld bead to be made between that flange edge and the outer edge of the header groove all around the flange without any likelihood of the heat from the welding operation damaging the bellows capsule. Thus, manufacture of the apparatus is facilitated because the bellows capsule can be completely fabricated and attached to the

bracket outside the apparatus and then the open end of that assembly can be welded to the header reliably all around the bellows capsule without adversely affecting the bellows capsule.

Since claim 1 does not include these features it does not enable the claimed invention to be carried out, contrary to the appellant's argument, and it is not properly supported by the description. The amended claim is not allowable under Articles 111(1), 102(3) and 84 EPC, accordingly.

Auxiliary request

3. *Amendments*

Claim 1 comprises claim 1 of the granted patent amplified to include all those features which are essential for successfully solving the technical problems set out in the patent in suit. As explained in point 2 above, these features mainly concern the constructional details of the mounting of the infusate chamber open end to the annular body which in turn is mounted in the groove in the manifold, and are fairly supported by the application as originally filed.

The amendments to the claim were made in response to the grounds of opposition since they more clearly demarcate the claimed apparatus from the cited prior art apparatus (Article 110(2), Rule 57a EPC). Since amended claims are on file, the opportunity was also taken to render the claim in the one-part form since the two-part form was clearly wrong in the case under consideration.

In the last part of claim 1 the words "promontory or" have been omitted, but this is not objectionable under Article 123(3) EPC since "promontory" and "mesa" are used interchangeably and as synonyms throughout the patent. Instead, the claim now states that the mesa is positioned at the second surface of the manifold and a corresponding promontory is provided in the upper annular shell.

The claim defines the depth of the groove in functional terms. The person skilled in the art will see this feature as a relationship between the depth of the walls of the groove and the thickness of the chamber in its fully collapsed condition, and is clear in the context. Moreover, no unreasonable effort would be required to implement the feature in practice.

The dependent claims 2 to 6 correspond to the dependent claims 3 to 7 as granted.

The appellant argues that an eccentric groove was disclosed only in connection with a catheter located in the space created by locating the groove eccentrically, so this claim includes an unjustified broadening of the feature. This objection is not well founded since the intention of the eccentric groove is to create space, it is not necessary to specify what goes in the space. This feature solves an ancillary problem, not the main problem of the patent, and the Board does not consider claim 3 to infringe Article 123(2) EPC.

The amendments are allowable, accordingly.

4. *Novelty*

The novelty of the device of claim 1 was not doubted by the appellant, a view also shared by the Board.

5. *Inventive step*

- 5.1 The combination of the features: the open end of the chamber is seated in the groove, the peripheral flange is connected by a fluid tight connection to the outer wall of the groove, and the groove is deep enough so that when the chamber is fully collapsed, its convolutions nest in the groove to a degree that positions the bellows end wall above the lower edge of the bracket of the body solve the technical problem of facilitating assembly of the infusate chamber, as described in the patent in column 4, lines 23 to 27 and column 8, lines 27 to 37, and also bring further advantages as described in column 8, lines 37 to 42.

These problems and advantages were not envisaged in the prior art, nor were the above constructional features which cooperate to solve the problems. The claim, therefore, involves an inventive step.

The appellant's argument, that if it were apparent to the person skilled in the art that a problem arose while welding the bellows to the manifold in E2 to E5, then the person skilled in the art would not only consider it obvious to make the groove deeper, this would in fact be compulsory, is not accepted by the Board since there is no evidence that the problem was recognised in the prior art. Moreover, even had the problem been known then it is not clear that the

present solution would have occurred to the person skilled in the art, since other solutions may be envisaged, such as providing a heat shield, etc.

Moreover, making the groove deeper in E2 to E5 would not be sufficient to solve the problem. That part of the annular member to which the open end of the bellows is attached in E2 to E5 is displaced from the bottom of the groove so that the open end is not seated in the groove. This arrangement prevents the bellows from collapsing fully into the groove.

- 5.2 The Board has also considered the prior art documents D1 and D6.

In D1 the infusate chamber does not nest inside a groove defined in the manifold (the housing portion 24a), it is accommodated in a space defined between the manifold and the housing lower shell, and there is no requirement to protect the infusate chamber from heat while the mounting means is attached to the groove wall. Since no groove is provided for mounting the infusate chamber this is attached to the housing upper and lower parts simultaneously (D1, column 4, lines 57 to 63).

The construction of the D6 device is similar in that the infusate chamber does not nest inside a groove defined in the manifold (if the cup-like member 14 is equated with a manifold), it is accommodated in a space defined between the manifold and the housing lower shell, and again there is no requirement to protect the infusate chamber from heat while the mounting means is attached to the groove wall. Here too the infusate

chamber is apparently attached to the housing upper and lower parts simultaneously (D1, column 4, lines 57 to 63).

Therefore, D1 and D6 are not relevant to the problem or solution of the patent in suit.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to maintain the patent in amended form on the basis of the following documents:

Claims 1 to 6 as submitted at the oral proceedings and named 1st auxiliary request, description and Figures as granted.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß