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Datasheet for the decision of 19 March 2009

Case Number: T 0213/07 - 3.2.02

Application Number: 99964755.5

Publication Number: 1139917

IPC: A61F 2/06

Language of the proceedings: EN

Title of invention:
Blood-flow tubing

Applicant:
Tayside Flow Technologies Limited

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56

Relevant legal provisions (EPC 1973):
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Keyword:
"Novelty, inventive step (no)"

Decisions cited:
T 0026/85, G 0005/83

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0213/07 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 19 March 2009

Appellant: Tayside Flow Technologies Limited
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 22 August 2006 refusing European application No. 99964755.5 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: D. Valle
Members: S. Chowdhury
A. Pignatelli

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal on 23 October 2006 against the decision of the examining division posted on 22 August 2006 refusing the European patent application 99964755. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 22 December 2006.

II. The application was refused for lack of novelty, clarity and extended subject-matter (Article 123(2) EPC) of the claims then on file.

III. The following documents are relevant for the present decision:

D8 = US - A - 4 743 480
D6 = WO - A - 93/15661

IV. Oral proceedings took place on 19 March 2009 upon request of the appellant.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims of a main request or of auxiliary requests one to four all filed with the statement of grounds dated 22 December 2006 or of auxiliary requests five and six filed with letter dated 19 February 2009 or of auxiliary request seven filed during the oral proceedings.

V. Claim 1 of the main request reads as follows:

"Tubing having internal helical flow inducing means (12), comprising a helical formation (14), adapted to induce helical flow in such fashion as to eliminate or reduce turbulence and/or eliminate or reduce dead flow regions in the tubing (11), and characterized by being artificial or modified natural blood flow tubing."

Claim 1 of the first auxiliary request differs from that of the main request in that the wording "helical formation" is substituted by: "internal grooving (14) and/or ridging".

Claim 1 of the second auxiliary request differs from that of the first auxiliary request in that the tubing is specified as "blood flow tubing" and the helical flow as "helical flow of blood passing through the tubing".

Claim 1 of the third auxiliary request recites:

"Use of tubing for the manufacture of a vascular prosthesis for inducing helical flow in such fashion as to eliminate or reduce turbulence and/or eliminate or reduce dead flow regions in the prosthesis (11), the tubing having internal helical flow inducing means (12) comprising internal helical growing (14) and/or ridging."

Claim 1 of the fourth and fifth auxiliary requests have both the additional feature with respect to claim 1 of the first auxiliary request that "the internal helical

growing (14) and/or ridging has a helix angle of between 5° and 16°".

Claim 1 of the sixth auxiliary request has the additional feature with respect to claim 1 of the fifth auxiliary request that the grooving or ridging is tapering in the direction of flow and/or in the opposite direction.

Claim 1 of the seventh auxiliary request is the same as claim 1 of the fifth auxiliary request.

Reasons for the Decision

1. The appeal is admissible.

2. *Novelty and inventive step*

D8 discloses a tubing having internal helical flow inducing means, comprising a helical formation (produced by a helical grooved extrusion tip, see column 1, lines 10 to 13), adapted to induce helical flow in such fashion as to reduce turbulence and/or reduce dead flow regions in the tubing, whereby the tubing is an artificial blood flow tubing (see column 1, lines 19 to 21; and column 6, lines 54 and 55).

The argument of the appellant that the tubing of D8 was not adapted to induce helical flow in such fashion as to reduce turbulence and/or reduce dead flow regions in the tubing is not convincing. Certainly, D8 does not explicitly disclose that the tube is adapted to perform

such function. However it is believed that the presence of helical formations almost necessarily, if not certainly, simply by channelling part of the fluid in definite spiralling paths between two adjacent helical formations, will induce helical flow and some level of laminar flow thereby reducing turbulence in some parts of the prosthesis.

The appellant's argument that the grafts of D8 had helical formations that were too tightly wound for helical flow to be conferred can not be followed since the disclosure of this document does not appear to contain specific limitations in that sense. The Computational Fluid Dynamics (CFD) study submitted by the appellant (see letter dated 2 March 2007) is not relevant for the decision since its results merely concern example 2 of D8 and are based on an arbitrary length of the graft of 150 mm, see page 11/13 of the CFD study.

D6 does not go against these conclusions. The passage of D6 cited by the appellant, that is page 11, first full paragraph and the corresponding Figures 1 to 3, are concerned with a helically shaped stent having an airfoil on internal surfaces thereof which induces a venturi effect increasing the velocity of the blood in order to reduce the possibility of thrombosis. The document does not appear to be concerned with the effect of helical formations on the flow.

Accordingly the subject-matter of claim 1 of the main request is not novel against D8.

D8 discloses also internal ridging, as the additional feature of claim 1 of the first auxiliary request (see column 1, lines 10 to 13), blood flow tubing, as the second auxiliary request (see column 6, lines 54 and 55) and the use of such tubing, as in the third auxiliary request.

The range of the helix angle of the internal helical ridging (between 5° and 16°) claimed in claims 1 of the fourth, fifth and seventh auxiliary request is partially known from D8, see column 3, line 6 (between 15° and 85°).

The applicant argues that even if there is an overlap between the claimed and the disclosed ranges, novelty could be recognized if the skilled person looking at the prior art would not seriously contemplate operating in the disclosed range, see decision of the board of appeal T 26/85. However, T 26/85 states that in such cases the prior art should contain a clear statement dissuading the person skilled in the art from using the overlapping values of the range, see point 13 of the reasons. D8 does not contain such statement. On the contrary, it states that the most preferable value for the angle is 45° (see column 3, line 17) which is closer to the lower values (15° to 16°) than to the higher value (85°) of the disclosed range.

Claim 1 of the sixth auxiliary request contains the distinguishing feature with respect to the disclosure of D8 that the ridging is tapering in the direction of flow and/or in the opposite direction.

The subject-matter of this claim does not involve an inventive step. The distinguishing feature is the result of mere workshop activity. The appellant argues that the tapering will improve the effect of reducing turbulence and/or dead flow regions. This assertion is however not supported by the original disclosure and is furthermore unlikely because tapering reduces the influence of the helical formations which are - according to the supposed invention - the very means for reducing turbulence, and also because inverting the direction of the tapering (in the direction of the flow vs. against the flow) would most likely invert also the effect on turbulence, contrary to what would be the desired effect of the claimed feature.

3. *Second medical indication*

Contrary to the argument of the appellant, claim 1 of the third auxiliary request is not a case of second medical indication.

According to G 5/83, a novelty objection can be overcome if a claim is directed to the use of a substance or composition for the manufacture of a medicament for a specific new and inventive therapeutic application. In this case what is claimed is a use of tubing for the manufacture of a vascular prosthesis. A prosthesis cannot be considered as a medicament. A medicament is as a rule a chemical substance which is consumed upon administration to the patient, whereas the prosthesis is a structural piece for the artificial replacement of a part of the body.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Sauter D. Valle