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**Datasheet for the decision
of 4 September 2008**

Case Number: T 1312/06 - 3.2.02

Application Number: 00932047.4

Publication Number: 1189651

IPC: A61M 25/00

Language of the proceedings: EN

Title of invention:
Composite drug delivery catheter

Applicant:
Durect Corporation

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC R. 103

Relevant legal provisions (EPC 1973):
EPC R. 67
EPC Art. 54, 56

Keyword:
"Novelty, inventive step (no)"
"Reimbursement of the appeal fee (no)"

Decisions cited:
-

Catchword:
-



Case Number: T 1312/06 - 3.2.02

DECISION
of the Technical Board of Appeal 3.2.02
of 4 September 2008

Appellant:
(Applicant)

Direct Corporation
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Representative:

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Decision under appeal:

Decision of the Examining Division of the
European Patent Office posted 6 February 2006
refusing European application No. 00932047.4
pursuant to Article 97(1) EPC 1973.

Composition of the Board:

Chairman: T. Kriner
Members: D. Valle
A. Pignatelli

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal on 13 April 2006 against the decision of the examining division posted on 6 February 2006 to reject the application. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 16 June 2006.

II. The application was rejected for lack of novelty (main request then on file) or inventive step (first to fourth requests then on file) having regard among other things to the document:

D3 = US - A - 5 782 797.

III. Oral proceedings were held on 4 September 2008.

As announced in the letter of 19 August 2008, the appellant did not appear at the oral proceedings.

IV. The appellant requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the main or the four auxiliary requests, all filed on 16 June 2006. Furthermore, he requested the reimbursement of the appeal fee on the ground of substantial procedural violations.

V. Claim 1 of the main request (which is identical with the main request forming the basis of the decision under appeal) reads as follows:

"A composite drug delivery catheter comprising:
at least one outer member (10) comprising a proximal end, a distal end, and an outer member body defining an outer member lumen, the outer member body comprising a substantially biocompatible material; and
at least one inner member (50) comprising a proximal end, a distal end, and an inner member body defining an inner member lumen, wherein the inner member is interposed within the outer member lumen so as to define an interstitial space (60) between the inner member and the outer member, the inner member lumen defining a drug delivery conduit (90) suitable for delivery of a drug from the inner member proximal end to the inner member distal end and the inner member body comprising a substantially impermeable material wherein the distal ends of the inner and outer members either terminate substantially within a single plane perpendicular to the distal ends, or the distal end of the outer member extends distally beyond the distal end of the inner member, and the outer member body is formed from a material different to that of the inner member body, the material of the outer member body having a lower flexural modulus than the material of the inner member body."

Claim 1 of the first auxiliary request differs from claim 1 of the main request in that the last feature according to which the material of the outer member body has a lower flexural modulus than the material of the inner member body has been replaced by the feature according to which the outer member has greater flexibility than the inner member.

Claim 1 of the second auxiliary request differs from claim 1 of the main request in that the feature according to which the material of the outer member body has a lower flexural modulus than the material of the inner member body has been replaced by the feature according to which the material of the outer member body has a flexural modulus in the range 703 to 3,515 kg/cm² and the material of the inner member body has a flexural modulus in the range 3,515 to 21,100 kg/cm².

Claim 1 of the third auxiliary request differs from claim 1 of the main request in that the last features according to which the outer member body is formed from a material different to that of the inner member body, the material of the outer member body having a lower flexural modulus than the material of the inner member body has been replaced by the feature according to which the outer diameter of the outer member is in the range 0.75 mm to 1.5 mm and the inner diameter of the inner member is in the range 0.05 mm to 0.15 mm.

Claim 1 of the fourth auxiliary request reads as follows (additional features with respect to the main request in italics):

"A drug delivery system including an implantable drug delivery device having a drug reservoir and a composite drug delivery catheter comprising:

at least one outer member (10) comprising a proximal end, a distal end, and an outer member body defining an outer member lumen, the outer member body comprising a substantially biocompatible material; and

at least one inner member (50) comprising a proximal end, a distal end, and an inner member body defining an inner member lumen, wherein the inner member is interposed within the outer member lumen so as to define an interstitial space (60) between the inner member and the outer member, the inner member lumen defining a drug delivery conduit (90) suitable for delivery of a drug from the inner member proximal end to the inner member distal end and the inner member body comprising a substantially impermeable material wherein the distal ends of the inner and outer members either terminate substantially within a single plane perpendicular to the distal ends, or the distal end of the outer member extends distally beyond the distal end of the inner member, and the outer member body is formed from a material different to that of the inner member body, the material of the outer member body having a lower flexural modulus than the material of the inner member body *the material of the outer member body having a flexural modulus in the range 703 to 3,515 kg/cm² and the material of the inner member body having a flexural modulus in the range 3,515 to 21,100 kg/cm², and the outer member having greater flexibility than the inner member the outer diameter of the outer member being in the range 0.75 mm to 1.5 mm, the inner diameter of the inner member being in the range 0.076 mm to 0.152 mm and the outer diameter of the inner member being in the range 0.127 mm to 0.305 mm, wherein the material of the inner member body is selected from a group consisting of a polymer, metal, glass, a polyolefin, nylon, polyethylene terephthalate, urethane, a fluoreneated polymer, poly(methyl) methacrylate, polyvinylidene chloride, laminous hydrophilic polymer, laminous hydrophobic*

polymer, acrylonitrile, nickel titanium, superelastic nickel titanium, and laminates of hydrophilic and hydrophobic polymers and the material of the outer member body is selected from a group consisting of silicone, polyethylene, an ethylene vinyl acetate copolymer, a polyvinylchloride, polymethylmethacrylate, polyethylmethacrylate, polymethacrylate, ethylene glycol dimethacrylate, ethylene dimethacrylate, hydroxymethyl methacrylate, polyurethane, polyvinylpyrrolidone, 2-pyrrolidone, polyacrylonitrile butadiene, a polycarbonate, polyamides, a fluoropolymers, a polystyrene, a styrene acrylonitrile homopolymer, a styrene acrylonitrile copolymer, cellulose acetate, an acrylonitrile butadiene styrene homopolymer, acrylonitrile butadiene styrene copolymer, polyvinylchloride, silicone rubber, polymethylpentene, a polysulfone, a polyester, a polyimide, polyisobutylene, polymethylstyrene, a polyvinyl chloride elastomer, a polyolefin homopolymeric elastomer, a polyolefine copolymeric elastomer, a urethane-based elastomer, a natural rubber, and a synthetic rubber."

VI. The appellant argued essentially as follows.

D3 was not detrimental to the novelty of the subject matter of the claims according to the present requests, since it disclosed a device where the distal end of the inner tubular member projected beyond the end of the outer tubular member.

Furthermore, no suitable flexural modulus figures were given for the inner and outer tubular members, and it was highly likely that the flexibility of the inner

tubular member was significantly greater than that of the outer tubular member.

The subject-matter of all present claims also involved an inventive step, in particular since the additional features provided in the auxiliary requests further distance the claimed invention from the prior art.

Reimbursement of the appeal fee was appropriate since the following combined procedural violations by the examining division formed a substantial violation:

- (i) a new document had been cited by the examining division after the expiry of the Rule 71a EPC deadline;
- (ii) the examining division refused to postpone the oral proceedings and thereby did not give the applicant sufficient time to submit written comments on the new prior art document;
- (iii) the examining division refused to allow the applicant the normal freedom in submitting further auxiliary requests to deal with the new prior art document.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request*

D3 (see in particular Figures 3a to 3d) discloses a composite drug delivery catheter (see column 7, lines 2 to 4) comprising one outer member (35) comprising a proximal end, a distal end, and an outer member body defining an outer member lumen, the outer member body comprising a substantially biocompatible material (see column 5, lines 54 to 58); and at least one inner member (25) comprising a proximal end, a distal end, and an inner member body defining an inner member lumen, wherein the inner member is interposed within the outer member lumen so as to define an interstitial space between the inner member and the outer member, the inner member lumen defining a drug delivery conduit suitable for delivery of a drug from the inner member proximal end to the inner member distal end and the inner member body comprising a substantially impermeable material (see column 5, lines 46 to 49) wherein the distal end of the outer member extends distally beyond the distal end of the inner member (see Figure 3a), and the outer member body is formed from a material different to that of the inner member body, the material of the outer member body (polyimide) having a lower flexural modulus than the material of the inner member body (steel).

The appellant's arguments with respect to novelty are not convincing. A device where the distal end of the inner tubular member projects beyond the end of the outer tubular member is only shown in Figure 2. However, the present novelty objection is based on the embodiment shown in Figure 3a to 3d, where the outer tubular member clearly projects beyond the inner

tubular member. With respect to the flexural modulus it is true that D3 does not disclose any figure for the inner and outer tubular member. However, it is known that the flexural modulus of polyimide is lower than that of steel.

Accordingly the subject-matter of claim 1 of the main request is not novel over the device disclosed in D3.

3. *First to third auxiliary requests*

With respect to the first to third auxiliary requests, D3 additionally discloses that the outer diameter of the outer member is in the range 0.75 mm to 1.5 mm (see column 5, lines 54-80: 0,030-0,050" = 0.76-1,27 mm). However, D3 does not disclose that

- (a) the outer member has greater flexibility than the inner member (see first auxiliary request).
- (b) the material of the outer member body has a flexural modulus in the range 703 to 3,515 kg/cm² and the material of the inner member body has a flexural modulus in the range 3,515 to 21,100 kg/cm² (see second auxiliary request); and
- (c) the inner diameter of the inner member is in the range 0.05 mm to 0.15 mm (see third auxiliary request).

Since it is well known that the body tissue comes in contact with the outer member of a catheter during its insertion into the body, the person skilled in the art would as a matter of course select a greater

flexibility for the outer member. This has to be regarded as a normal workshop activity without any inventive skill being involved.

The claimed ranges of values for the flexural modulus (feature b) overlap (at 3,515 kg/cm²) and are very broad. Hence no meaningful problem-solution reasoning can be devised for this feature, and the claimed selection has to be considered as not reaching beyond a normal workshop activity.

The selection of the inner diameter of the inner member according to feature c is an obvious design option, in particular when small dosages of drug have to be delivered through the inner member.

Consequently, the subject-matter of claim 1 of the first to third auxiliary requests does not involve an inventive step.

4. *Fourth auxiliary request*

With respect to the fourth auxiliary request, D3 discloses the further features, that the material of the inner member body is a metal and that the material of the outer member body is polyimide.

However D3 does not disclose that

- (a) the outer member has greater flexibility than the inner member;
- (b) the material of the outer member body has a flexural modulus in the range 703 to 3,515 kg/cm²

and the material of the inner member body has a flexural modulus in the range of 3,515 to 21,100 kg/cm²;

(c') the outer diameter of the outer member is in the range of 0.75 mm to 1.5 mm, and the inner diameter of the inner member is in the range of 0.076 mm to 0.152 mm; and

(d) the outer diameter of the inner member is in the range of 0.127 mm to 0.305 mm.

As already pointed out above, the provision of features a and b in a device according to D3 is obvious.

Feature c' differs only slightly from feature c of the second auxiliary request (see above). Accordingly also feature c' is considered as obvious.

Finally, also the selection of the outer diameter of the inner member is considered as an obvious design option which does not require an invention activity.

Therefore, also the subject-matter of claim 1 of the fourth auxiliary request does not involve an inventive step.

5. *Reimbursement of the appeal fee*

In order to be entitled for reimbursement of the appeal fee, the EPC (see the old version (Rule 67) and the new version (Rule 103)) requires that the appeal be allowed. Since this is not the case here, the request has to be refused.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

T. Kriner