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Datasheet for the decision of 21 October 2008

Case Number: T 1372/06 - 3.2.02

Application Number: 03251316.0

Publication Number: 1342481

IPC: A61M 5/142

Language of the proceedings: EN

Title of invention:
Convection-enhanced implantable drug delivery device

Applicant:
Codman & Shurtleff, Inc.

Opponent:
-

Headword:
-

Relevant legal provisions:
-

Relevant legal provisions (EPC 1973):
EPC Art. 54

Keyword:
"Novelty (yes, after amendments)"

Decisions cited:
-

Catchword:
-

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Case Number: T 1372/06 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 21 October 2008

Appellant: Codman & Shurtleff, Inc.
325 Paramount Drive
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Massachusetts 02767-0350 (US)

Representative: Mercer, Christopher Paul
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 17 March 2006 refusing European application No. 03251316.0 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 26 May 2006 against the decision of the examining division posted on 17 March 2006 to refuse the application. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 27 July 2006.

II. The examining division held that the subject-matter of the main and auxiliary requests then on file lacked novelty with respect to the following documents

D1 = WO - A - 01/35928, and
D6 = US - A - 4 596 575.

III. Oral proceedings were held on 21 October 2008.

At the end of the oral proceedings the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 34 as filed during the oral proceedings.

IV. Claim 1 reads as follows:

"An implantable drug delivery system (10) comprising: an infusion pump (20) including a fluid outlet; a first catheter (40) extending directly from the fluid outlet to a discharge portion positionable directly at a target tissue site; and a controlled release drug assembly (30) configured for controllably releasing drug material, wherein: said drug assembly (30) is in direct communication with said first catheter (40) such that the drug material is released directly into said

first catheter (40); the pump (20) is effective to deliver a carrier fluid to the fluid outlet such that the drug material released into the first catheter (40) discharges directly at the discharge portion to treat the target tissue site; and the drug assembly (30) is in fluid communication with the first catheter (40) intermediate the pump and the target tissue site; and the system includes a controller (32a) configured to initiate drug release out of phase with the operation of the infusion pump (20) such that the drug material is released into the first catheter (40) before flow in the first catheter (40) is initiated".

Claims 2 to 34 are dependent on claim 1.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

Claim 1 is based on the originally filed claim 1, on the disclosure on page 10, lines 2 to 6, page 7, first full paragraph of the originally filed description, and on Figure 1 as originally filed.

Hence the amended claim 1 is allowable with respect to Article 123(2) EPC.

3. *Novelty*

D1 and D6 (the teaching of which is included in D1 by reference) disclose in combination an implantable drug

delivery system (see D6, Figure 1, reference number 9, and column 2, lines 30 - 32) comprising an infusion pump (3, 4) including a fluid outlet (opening of 45); a first catheter (conduit 45 and feed tube 7, considered as a catheter within the meaning of the invention, since a catheter is a tube that can be inserted into a body cavity, duct or vessel) extending directly from the fluid outlet to a discharge portion positionable directly at a target tissue site; and a controlled release drug assembly (microchip device, see D1, page 30, lines 24 to 29) configured for controllably releasing drug material, wherein the pump is effective to deliver a carrier fluid to the fluid outlet such that the drug material released into the first catheter discharges directly at the discharge portion to treat the target tissue site.

Contrary to the appellant's opinion, D1/D6 additionally disclose that the drug assembly is in direct communication with the first catheter such that the drug material is released directly into the first catheter and that the drug assembly is in fluid communication with the first catheter intermediate the pump and the target tissue site.

According to D1 (see page 30, lines 27 to 30) the micropump shown in D6 pumps the carrier fluid across one or more surfaces of the microchip device disclosed in D6. For the skilled person this means that the microchip device is positioned downstream of the micropump. The appellant's argument that this statement in the context of D6 could also suggest that the microchip lies on the suction side of the micropump is not convincing. The word "pumps" used in D6 clearly

means an arrangement of the microchip on the pumping side. By contrast an arrangement on the suction side would have been referred to by the word "sucks".

However, D1/D6 does not disclose that the system includes a controller configured to initiate a drug release out of phase with the operation of the infusion pump (20) such that the drug material is released into the first catheter before flow in the first catheter is initiated.

Accordingly claim 1 is novel over the teaching of D1 and D6.

4. *Procedural matters*

The decision under appeal dealt only with the issue of novelty. The newly added features to claim 1 have been taken from the description and therefore obviously not yet considered by the first instance. In consideration of the above, the board sees it as appropriate to remit the case to the first instance for further prosecution.

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 for further prosecution on the basis of claims 1 to 34 filed during the oral proceedings on 21 October 2008.

The Registrar: The Chairman:

V. Commare T. Kriner