

**Internal distribution code:**

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

**Datasheet for the decision  
of 19 September 2017**

**Case Number:** T 0413/14 - 3.2.02

**Application Number:** 06802065.0

**Publication Number:** 1928557

**IPC:** A61M25/00, A61M25/098

**Language of the proceedings:** EN

**Title of invention:**

REFLUX RESISTANT CANNULA AND SYSTEM FOR CHRONIC DELIVERY OF  
THERAPEUTIC AGENTS USING CONVECTION-ENHANCED DELIVERY

**Applicant:**

The Regents of the University of California

**Headword:**

**Relevant legal provisions:**

EPC Art. 123(2)  
RPBA Art. 13

**Keyword:**

Late-filed auxiliary requests - admitted (yes)  
Amendments - added subject-matter (no)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

European Patent Office  
D-80298 MUNICH  
GERMANY  
Tel. +49 (0) 89 2399-0  
Fax +49 (0) 89 2399-4465

Case Number: T 0413/14 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 19 September 2017**

**Appellant:** The Regents of the University of California  
(Applicant) 1111 Franklin Street, 12th Floor  
Oakland, CA 94607 (US)

**Representative:** Harrison, Susan Joan  
Mewburn Ellis LLP  
City Tower  
40 Basinghall Street  
London EC2V 5DE (GB)

**Decision under appeal:** **Decision of the Examining Division of the European Patent Office posted on 10 September 2013 refusing European patent application No. 06802065.0 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman** E. Dufrasne  
**Members:** P. L. P. Weber  
D. Ceccarelli

## **Summary of Facts and Submissions**

I. The appeal of the applicant is against the decision of the Examining Division posted on 10 September 2013 refusing the application because of lack of compliance with Article 123(2) EPC.

II. The notice of appeal was filed on 19 November 2013 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was filed on 20 January 2014.

III. Oral proceedings were held on 19 September 2017.

The appellant requested that the decision be set aside and that a patent be granted on the basis of one of the first and second auxiliary claim requests filed during the oral proceedings.

The main request, filed with letter dated 7 January 2013, was withdrawn.

IV. Claim 1 according to the first auxiliary claim request reads as follows:

"A cannula (200) for chronic convection-enhanced delivery of substances to the brain; the cannula comprising:

a tubular body (202) having a proximal end (204) and a distal end (206) and having a central lumen (212) between said proximal (204) and distal (206) ends; and

an infusion tube (210) positioned in said central lumen (212);

characterised in that the infusion tube (210) extends beyond said distal end (206) of said tubular body (202) to form a rigid delivery tip (24) of fixed length and having a smaller diameter than the distal end (206) of the tubular body (202) such that said cannula has a plurality of outer surface segments of varying diameter and length;

wherein the diameter of each said outer surface segment is substantially uniform along the length of the segment;

wherein the length and diameter of said outer surface segments are selected to reduce reflux during convection-enhanced delivery of substances to the brain; and

wherein said cannula (200) shows no backflow beyond said delivery tip at flow rates of up to 10  $\mu$ l/min."

### **Reasons for the Decision**

1. The appeal is admissible.
2. Convection-enhanced delivery (CED) is a direct intracranial drug delivery technique which is promising for the treatment of various diseases affecting in the central nervous system that respond poorly to systemic chemotherapy or surgical treatment. There is, however, no standardised catheter design which permits a good infusion rate without reflux. This is a major obstacle to broad clinical use. The invention proposes a stepped cannula which minimises reflux.
3. Admissibility of the auxiliary claim requests

Although the first and second auxiliary claim requests were filed during the oral proceedings, the Board decided to admit them under Article 13 RPBA because claim 1 of both requests complied *prima facie* with Article 123(2) EPC, by basically returning to claim 1 of the application as filed.

4. Added subject-matter

Present claim 1 is mainly based on claim 1 of the application as filed,

with the following feature deleted:

*i) wherein the relative diameters of said outer surface segments decreases stepwise from the proximal end to the distal end,*

and the following features added:

*ii) the infusion tube (210) extends beyond said distal end (206) of said tubular body (202) to form a rigid delivery tip (24) of fixed length and having a smaller diameter than the distal end (206) of the tubular body (202),*

*iii) wherein said cannula (200) shows no backflow beyond said delivery tip at flow rates of up to 10  $\mu$ l/min.*

4.1 Deletion of feature i) and addition of feature ii)

The Board notes that for the claimed cannula it is explicitly stated in feature ii) that the diameter of the infusion tube is smaller than the diameter of the tubular body, so that the condition of feature i) is

satisfied for these two segments, as would have been the case for an embodiment with two segments falling under the original wording of the claim. The Board further considers that, should the cannula have more than two segments, then feature i) would be implicit from the intended use in the brain and the desire to minimise damage to it ([0042]). Moreover, all embodiments presented in the description show a stepwise decrease in the outer diameter of the segments from the proximal end towards the distal end of the cannula. The deletion of feature i) from claim 1 of the application as filed therefore does not add matter; nor does the addition of feature ii).

#### 4.2 Addition of feature iii)

From all the tests presented in the description, particularly from that with the cannula for use in human brains, it is clear that the flow rate of 10  $\mu$ l/min represents a limit above which reflux is more likely to occur (e.g. [0085], [00118], Figures 17E and 17D). The tested cannula for use with human brains was a four-step cannula, the diameter of the segments diminishing from 5mm to 0.33mm. More precisely, the distal tip was 10mm long, preceded by a segment having a length of 10mm with a diameter of 0.64mm, preceded by a segment having a length of 124mm and a diameter of 2.1mm (e.g.[0101]). Although described in a precise context, the Board accepts that the flow-rate limitation feature now mentioned in the claim does not add matter because it has to be read in combination with the two preceding features of the claim explicitly indicating that the reduced reflux is to be obtained by properly selecting the length and diameter of said outer surface segments, which should additionally have a substantially uniform diameter along their length.

This general teaching was already present in claim 1 of the application as filed.

4.3 Additional minor amendment

That the infusion tube should form a rigid delivery tip is for instance implicit from claim 4 of the application as filed, but also from the fact that at least a part of the infusion tube should be made of fused silica (e.g. [00118] "the silica tip was cut at 10mm from the distal (needle end)"(sic)).

4.4 Claim 1 of the first auxiliary claim request therefore fulfils the requirements of Article 123(2) EPC.



## 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 department for further prosecution on the basis of the first auxiliary claim request as filed during the oral proceedings.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated