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**Datasheet for the decision  
of 12 September 2006**

**Case Number:** T 0448/05 - 3.3.02

**Application Number:** 97908818.4

**Publication Number:** 0885002

**IPC:** A61K 9/06

**Language of the proceedings:** EN

**Title of invention:**

Materials and methods for enhancing cellular internalization

**Applicant:**

THE PENN STATE RESEARCH FOUNDATION, et al

**Opponent:**

-

**Headword:**

Composition for cellular internalization/THE PENN STATE  
RESEARCH FOUNDATION

**Relevant legal provisions:**

EPC Art. 84, 123(2)

**Keyword:**

"Added matter (no) "

**Decisions cited:**

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**Catchword:**

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Case Number: T 0448/05 - 3.3.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.02  
of 12 September 2006

**Appellants:**

THE PENN STATE RESEARCH FOUNDATION  
207 Old Main Building  
University Park, PA 16802 (US)

MASSACHUSETTS INSTITUTE OF TECHNOLOGY  
77 Massachusetts Avenue  
Cambridge, MA 02139 (US)

**Representative:**

Bassett, Richard Simon  
Eric Potter Clarkson LLP  
Park View House  
58 The Ropewalk  
Nottingham NG1 5DD (GB)

**Decision under appeal:**

Decision of the Examining Division of the  
European Patent Office posted 16 November 2004  
refusing European application No. 97908818.4  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** U. Oswald  
**Members:** J. Riolo  
P. Mühlens

## Summary of Facts and Submissions

- I. European patent application No. 97 908 818.4 published as WO 97/32572 under the Patent Cooperation Treaty (Article 158(1) EPC) was refused by a decision of the Examining Division posted on 16 November 2004 on the grounds of Articles 123(2) and 84 EPC.
- II. The decision was based on claims 1 to 26 of the main request, claims 1 to 26 of the first auxiliary request and claims 1 to 26 of the second auxiliary request all filed during the oral proceedings before the Examining Division.
- III. According to the decision under appeal, the Examining Division was of the opinion that the European patent application did not fulfil the requirements of Articles 123(2) EPC (main request and auxiliary request 1) and 84 EPC (auxiliary request 2).

In the Examining Division's opinion claim 1 of the Main Request did not comply with the requirement of Article 123(2) EPC, because the application as filed did not disclose a combination of the ranges of 1-2000 Poise apparent viscosity measured at an applied stress range of 1-10 Pascals.

Claim 1 of the first auxiliary request did not comply with the requirement of Article 123(2) EPC, because the requirement that the viscosity of the composition must be matched to the viscosity of the cytosol ("roughly the same") was deleted, so that the application contained added matter which was not disclosed in the application as filed.

As the subject-matter of amended claim 1 of the second auxiliary request, it was considered that the feature "characterised in that the composition has an apparent viscosity roughly equal to the viscosity of the cytoplasm of a cell which is between 1 and 2000 Poise" lacked clarity.

Accordingly, all requests were rejected.

- IV. The appellant (applicant) lodged an appeal against this decision.
  
- V. Oral proceedings were held on 12 September 2006.

During the oral proceedings, the appellant filed a main request and auxiliary request 1. He further maintained auxiliary requests 2 and 4 and withdrew auxiliary request 3, which were all filed with the grounds of appeal.

Independent claim 1 of the main request reads as follows:

"A composition for administration of an agent intracellularly to a cell, comprising: a biocompatible hydrogel, lipogel or sol, and an agent to be delivered, the agent binding to or interacting with a receptor on the cell surface, or being covalently or noncovalently attached to a molecule binding to or interacting with a receptor on the cell surface, or being incorporated in a carrier including a ligand binding to or interacting with a cell surface receptor; characterised in that the composition has an apparent viscosity of between 1 and 200 Poise when measured using a controlled stress

rheometer at 37°C using a cone-and-plate geometry at an applied stress range of between 1 and 100 Pascals".

The appellant argued that the subject matter of claim 1 of the main request was clear and supported by the documents as filed.

- VI. The appellant requested that the decision under appeal be set aside and that the case be remitted to the first instance for further prosecution on the basis of the main request filed in the oral proceedings or on the basis of the first auxiliary request filed in the oral proceedings, or on the basis of the second auxiliary request filed with letter dated 30.03.2006, or on the basis of a third auxiliary request filed as fourth auxiliary request with letter dated 30.03.2006.

### **Reasons for the Decision**

1. The appeal is admissible.
2. *Main request*
  - 2.1 Claim 1 of the main request mainly differs from claim 1 of the first auxiliary request underlying the decision under appeal in that the apparent viscosity range has been restricted to a range lying between 1 and 200 Poise. In addition the word "improving" has been deleted.
  - 2.2 The present wording of claim 1 satisfies the requirements of Article 84 EPC.

The claimed composition is defined in terms of clear and unambiguous features, namely, its components and its apparent viscosity together with an indication of the method and conditions used to measure that parameter which allow it to be reliably determined.

Concerning the scope of the characterising feature of the claim, the Board considers that the broadest technically meaningful interpretation should be taken into account, namely, that at some point within the applied stress range of between 1 and 100 Pascals, the apparent viscosity of the composition must lie between 1 and 200 Poise. This interpretation is supported by the examples (see Example 1 and Figure 1) and was confirmed by the appellant.

### 2.3 Article 123(2) EPC

Independent claim 1 is based on claim 19 as originally filed in combination with claim 25 wherein the upper limit of the apparent viscosity has been restricted according to a preferred value found on page 13, line 7 and that of the applied stress range according to page 13, line 10 of the application as originally filed. The basis for the specification that the viscous fluid is a hydrogel, lipogel or sol can be found in claim 32.

The method of measurement "using a controlled stress rheometer at 37°C using a cone-and-plate geometry" introduced into claim 1 is drawn from example 1 (page 20, lines 12-15) whereby the temperature of 37°C is given in Figure 1. In the description on page 13, lines 7-8 it is stated that the "apparent viscosity can

be measured by a standard rheometer". The Board can accept the appellant's argument that the person skilled in the art on reading this statement would inevitably turn to the only specific method of measurement disclosed in the application as originally filed, which is that disclosed in example 1, and would recognise this as being a representative method of measurement to be used in a more general context in determining the apparent viscosity, particularly since the apparent viscosity and applied stress ranges given in Figure 1 were clearly illustrative of the corresponding values given on page 13, lines 5-10, and the temperature of 37°C corresponded to body temperature reflecting the medical application of the claimed compositions disclosed throughout the specification, for example at page 3, lines 14-15, page 4, lines 1-8 and claims 15 to 17 as originally filed.

Finally, the phrase "wherein the composition has roughly the same apparent viscosity ... as the cytosolic fluid of the cell to which the agent is to be delivered" has been deleted from originally filed claim 19.

In the decision under appeal, the Examining Division argued in relation to the auxiliary request 1 that the feature of matched viscosities implied a limitation in scope and could not be deleted without contravening of Article 123(2) EPC. Doubts regarding this point were reinforced owing to the discrepancy between the values given for typical cytosol viscosities of 50-200 Poise (page 12, lines 20-21) compared to the range of 1-2000 Poise claimed.

The Board agrees with the Examining Division that the application as originally filed teaches that the compositions according to claim 19 in combination with claim 25, namely, compositions having an apparent viscosity between 1 and 2000 Poise at a shear stress of between 1 and 200 Pascals, have to be further adapted to the viscosity of the target cell (see page 13, lines 5 to 16).

This does not, however, change the fact that these compositions as such, ie these compositions prior to their adaptation to the viscosity of the target cell or prior to the selection of the compositions having the suitable viscosity, are disclosed in the application as originally filed.

For these reasons, the Board concludes that claim 1 of the main request meets the requirements of Article 123(2) EPC.

3. *Remittal*

It follows from the above that the subject matter of claim 1 of the main request fulfils the requirements of Articles 84 and 123(2) EPC. The examination of the present application should therefore proceed on the basis of the text as amended according to the appellant's main request.

Having so decided, the Board has not taken a decision on the whole matter since the decision under appeal was solely based on deficiencies of claim 1 with respect to Articles 84 and 123(2) EPC. It is noted that the Examining Division has not yet ruled on the other

dependent and independent claims with respect to Articles 84 and 123(2) EPC and on the other requirements for granting a European patent, and these issues clearly require careful consideration.

With respect to the issue of novelty, the Examining Division is referred to the scope of present claim 1 as construed under paragraph 2.2 above. It is noted that the use of a different parameter by which to define a particular product cannot by itself give the product novelty.

As to the assessment of inventive step, it is pointed out that the question of whether an effect can be shown over the whole claimed viscosity range could be relevant for the present case (arbitrary choice vs purposive selection).

In the light of the above findings, it is not necessary to consider the appellant's auxiliary requests.

**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.

The Registrar

The Chairman

D. Sauter

U. Oswald