

**Internal distribution code:**

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

**Datasheet for the decision  
of 22 January 2014**

**Case Number:** T 1213/10 - 3.2.02

**Application Number:** 08157038.4

**Publication Number:** 1997425

**IPC:** A61B 5/00, A61B 5/103

**Language of the proceedings:** EN

**Title of invention:**

Method and apparatus for measuring enzymatic activity by use  
of laser

**Applicant:**

Sony Corporation

**Headword:**

-

**Relevant legal provisions:**

EPC Art. 53(c), 123(2)

**Keyword:**

"Method for treatment by surgery and therapy (yes, main  
request and auxiliary requests 1, 3 and 4)"

"Added subject-matter (yes, auxiliary requests 2 and 5)"

**Decisions cited:**

G 0001/07, T 0383/03

**Catchword:**

-



Case Number: T 1213/10 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 22 January 2014

**Appellant:**  
(Applicant)

Sony Corporation  
1-7-1 Konan, Minato-ku  
Tokyo 108-0075 (JP)

**Representative:**

Körber, Martin Hans  
Mitscherlich & Partner  
Patent- und Rechtsanwälte  
Sonnenstrasse 33  
D-80331 München (DE)

**Decision under appeal:**

**Decision of the Examining Division of the  
European Patent Office posted on 21 January  
2010 refusing European patent application  
No. 08157038.4 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman:** E. Dufrasne  
**Members:** M. Stern  
C. Körber

## **Summary of Facts and Submissions**

- I. The applicant lodged an appeal against the decision of the Examining Division dispatched on 21 January 2010 refusing European application No. 08 157 038.4. The Examining Division held inter alia that the claimed method was a method of surgery and a method of therapy within the meaning of Article 53(c) EPC.
- II. Notice of appeal was received on 18 March 2010 and the fee for appeal was paid on that same day. The statement setting out the grounds of appeal was received on 21 May 2010.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the claims according to the main request or to one of the first to fifth auxiliary requests, all filed on 21 May 2010. As a further auxiliary request, oral proceedings were requested.

- III. In an annex to the summons to oral proceedings dated 18 October 2013, the Board presented its provisional opinion concerning inter alia the requirements under Articles 53(c) and 123(2) EPC.

In a letter dated 27 November 2013, the appellant presented no further arguments, withdrew its request for oral proceedings and indicated that its representative would not attend the oral proceedings if the Board still held them.

IV. Oral proceedings were held on 22 January 2014 and the proceedings were continued without the appellant (Rule 115(2) EPC, Article 15(3) RPBA).

V. Claim 1 of the different requests reads as follows (additions to the main request are underlined, deletions are struck through):

**Main request:**

"1. A method of measuring an enzymatic activity, comprising  
measuring the quantity of a substrate metabolite produced upon metabolism of a substrate by an enzyme, through detecting a radiant wave generated from a multiple photon excitation process of said substrate or said substrate metabolite,  
characterized in that  
said substrate is caused by a penetration device (5) to penetrate to a site where said enzyme is present, and  
the measuring is performed in the presence of an enzymatic activity promoter or inhibitor."

**First auxiliary request:**

"1. A method of measuring an enzymatic activity, comprising  
measuring the quantity of a substrate metabolite produced upon metabolism of a substrate by an enzyme, through detecting a radiant wave generated from a multiple photon excitation process of said substrate or said substrate metabolite,  
characterized in that

said substrate is caused by a feed line (53) and a penetrating part (52) of a penetration device (5) to penetrate to a site where said enzyme is present, and the measuring is performed in the presence of an enzymatic activity promoter or inhibitor, and said promoter or inhibitor is caused by at least one further feed line (53) and penetration part (52) of said penetration device (5) to penetrate to the site where said enzyme is present."

***Second auxiliary request:***

"1. A method of measuring an enzymatic activity under in vitro conditions, comprising measuring the quantity of a substrate metabolite produced upon metabolism of a substrate by an enzyme, through detecting a radiant wave generated from a multiple photon excitation process of said substrate or said substrate metabolite, characterized in that said substrate is caused by a feed line (53) and a penetrating part (52) of a penetration device (5) to penetrate to a site where said enzyme is present, and the measuring is performed in the presence of an enzymatic activity promoter or inhibitor, and said promoter or inhibitor is caused by at least one further feed line (53) and penetration part (52) of said penetration device (5) to penetrate to the site where said enzyme is present."

***Third auxiliary request:***

"1. A method of measuring an enzymatic activity, comprising

measuring the quantity of a substrate metabolite produced upon metabolism of a substrate by an enzyme, through detecting a radiant wave generated from a multiple photon excitation process of ~~said substrate or~~ said substrate metabolite,

characterized in that

said substrate is caused by a penetration device (5) to penetrate to a site where said enzyme is present, and

~~the measuring is performed in the presence of an enzymatic activity promoter or inhibitor~~ the substrate has a coumarin skeleton."

***Fourth auxiliary request:***

"1. A method of measuring an enzymatic activity, comprising

measuring the quantity of a substrate metabolite produced upon metabolism of a substrate by an enzyme, through detecting a radiant wave generated from a multiple photon excitation process of ~~said substrate or~~ said substrate metabolite,

characterized in that

said substrate is caused by a penetration device (5) to penetrate to a site where said enzyme is present, and

~~the measuring is performed in the presence of an enzymatic activity promoter or inhibitor~~ the substrate comprises 7-Methoxy-trifluoromethylcoumarin, MFC."

***Fifth auxiliary request:***

"1. A method of measuring an enzymatic activity, under in vitro conditions comprising

measuring the quantity of a substrate metabolite produced upon metabolism of a substrate by an enzyme, through detecting a radiant wave generated from a multiple photon excitation process of ~~said substrate or~~ said substrate metabolite,

characterized in that

said substrate is caused by a feed line (53) and apenetrating part (52) of a penetration device (5) to penetrate to a site where said enzyme is present, and

the measuring is performed in the presence of an enzymatic activity promoter or inhibitor,

said promoter or inhibitor is caused by at least one further feed line (53) and penetration part (52) of said penetration device (5) to penetrate to the site where said enzyme is present, and

the substrate comprises 7-Methoxy-trifluoromethylcoumarin, MFC."

VI. The arguments of the appellant presented in the statement of grounds of appeal which are relevant for the present decision are summarised as follows:

- The claimed method was not directed to a treatment within the meaning of Article 53(c) EPC, but was directed to measuring an enzymatic activity in general which could be used for scientific or analytical purposes. The method was not performed for the immediate health of a patient. Especially the step of penetrating the substrate to a site where the enzyme was present did not achieve any curative benefit, but simply enhanced the accuracy and resolution of the multi-photon excitation process measurement. Decision T 383/03 restricted the meaning of "treatment by surgery" to curative treatments.

- The method defined in the second and fifth auxiliary requests was now exclusively directed to its being performed under in vitro conditions, which were disclosed in the description for example on page 14, line 5. The method was therefore no longer performed on the human or animal body, and was thus not excluded from patentability under Article 53(c) EPC.

### **Reasons for the Decision**

1. The appeal is admissible.
2. *Main request - Article 53(c) EPC*
  - 2.1 The claimed method is a "method of measuring an enzymatic activity comprising measuring the quantity of a substrate metabolite produced upon metabolism of a substrate by an enzyme, ... (wherein) the substrate is caused by a penetration device to penetrate to a site where said enzyme is present, ..."
  - 2.2 According to certain examples presented in the description, the measurement of an enzymatic activity is carried out in viscus tissue ("the site where said enzyme is present"), such as liver, brain, kidney, muscles, etc., by performing endoscopy (page 22, lines 8 to 18). That is, in these examples, which fall under the terms of claim 1, the substrate is introduced into said viscus tissue using a "penetration device" such as an endoscope. Endoscopic manipulation of said viscus tissue is, however (following G 1/07, point 1 of the Order), *"an invasive step representing a*



*substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails a substantial health risk even when carried out with the required professional care and expertise". Moreover, G 1/07 makes it clear that "[a] claim which comprises a step encompassing an embodiment which is a 'method for treatment of the human or animal body by surgery' within the meaning of Article 53(c) EPC cannot be left to encompass that embodiment" (point 2a of the Order), and "a method claim falls under the prohibition of patenting methods for treatment by therapy or surgery now under Article 53(c) EPC if it comprises or encompasses at least one feature defining a physical activity or action that constitutes a method step for treatment of a human or animal body by surgery or therapy" (point 3.2.5 of the Reasons).*

It hence follows that the present method, which comprises a method step encompassing such invasive interventions as endoscopic manipulations of viscus tissue, is excluded from patentability as a method for treatment of the human or animal body by surgery.

- 2.3 The appellant argued that the claimed method was patentable since it was directed to measuring an enzymatic activity in general which could be used for scientific or analytical purposes, and that the method was not performed for the immediate health of a patient and did not achieve a curative benefit (T 383/03).

However, in G 1/07, which extensively dealt with T 383/03 and the curative aspect of surgery developed therein, the Enlarged Board came to the conclusion that

*"neither the legal history nor the object and purpose ("ratio legis") of the exclusions from patentability in Article 53(c) EPC justify a limitation of the term 'treatment by surgery' to curative surgery"* (point 3.3.10 of the Reasons).

Accordingly, the present Board considers that the appellant's arguments are not relevant for deciding the question of patentability under Article 53(c) EPC.

2.4 Consequently, the method of claim 1 of the main request constitutes a method for treatment of the human or animal body by surgery within the meaning of Article 53(c) EPC.

2.5 The application describes moreover that certain drugs, such as antidepressants or antiarrhythmic agents, serve as "substrates" which are introduced into the tissue in which the enzymatic activity is measured (page 11, lines 16 to 21).

Insofar as the method of claim 1 of the main request encompasses the administration of these drugs, and following again point 3.2.5 of the Reasons of G 1/07 which also relates to therapy, the claimed method is also a method of treatment of the human or animal body by therapy within the meaning of Article 53(c) EPC.

3. *First, third and fourth auxiliary requests - Article 53(c) EPC*

Claim 1 of the first, third and fourth auxiliary requests includes additional limitations but leaves unchanged the aforementioned method step which

encompasses methods for treatment of the human or animal body by surgery. Therefore, following the aforementioned reasoning in relation to methods for treatment by surgery, claim 1 of these requests is likewise not allowable under Article 53(c) EPC.

4. *Second and fifth auxiliary requests - Article 123(2) EPC*

4.1 Claim 1 of the second and fifth auxiliary requests has been limited to measuring an enzymatic activity "*under in vitro conditions*".

4.2 The appellant indicated in its statement of grounds of appeal that the "in vitro" limitation was disclosed in the description on page 14, line 5.

However, the "*in vitro conditions*" explained on page 14 are such that the substrate is contained in a buffer, which is not a substrate "*caused by a feed line (53) and a penetrating part (52) of a penetration device (5) to penetrate to a site where said enzyme is present*" as defined in claim 1. The step of causing the substrate to penetrate to a site where the enzyme is present using a penetration device is disclosed in the original application only for measurements under "*in vivo conditions*", in which the enzyme is in fact present inside in vivo tissue or an in vivo cell (page 14, lines 16 to 21 and page 30, lines 7 to 14). Only under these in vivo conditions is it pertinent to speak of causing the substrate to penetrate or permeate to the site where the enzyme is present, and to use for that purpose a penetration device (page 30, lines 19 to 25).

Furthermore, the original application does not disclose either that under "in vitro conditions" an enzymatic activity "promoter or inhibitor is caused by at least one further feed line (53) and penetration part (52) of said penetration device (5) to penetrate to the site where said enzyme is present", as also defined in claim 1 (page 14, line 23 to page 15, line 2).

- 4.3 There is consequently no basis in the original application for the "in vitro" limitation recited in claim 1 of the second and fifth auxiliary requests. The methods thus defined therefore extend beyond the content of the application as originally filed, contrary to Article 123(2) EPC.

## **Order**

### **For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:

D. Hampe

E. Dufrasne