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**Datasheet for the decision
of 10 November 2006**

Case Number: T 1264/05 - 3.3.04

Application Number: 99950172.9

Publication Number: 1121140

IPC: A61K 38/17

Language of the proceedings: EN

Title of invention:

Method for screening for anti-amyloidogenic properties and
method for treatment of neurodegenerative disease

Applicant:

The Regents of the University of California

Opponent:

-

Headword:

Screening for anti-amyloidogenic properties/UNIVERSITY OF
CALIFORNIA

Relevant legal provisions:

EPC Art. 123(2)

Keyword:

"New main request: added subject-matter (no)"

Decisions cited:

-

Catchword:

-



Case Number: T 1264/05 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 10 November 2006

Appellant: The Regents of the University of California
Office of Technology Transfer
9500 Gilman Drive, Mail Box 0910
La Jolla, CA 92093-0910 (US)

Representative: Gates, Marie Christina Esther
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 25 April 2005
refusing European application No. 99950172.9
pursuant to Article 97(1) EPC.

Composition of the Board:

Chair: U. Kinkeldey
Members: R. Gramaglia
R. Moufang

Summary of Facts and Submissions

- I. The appeal lies against the decision of the examining division posted 25 April 2005 refusing the European patent application No. 99 950 172.9 pursuant to Article 97(1) EPC. Said European patent application originated from an international application under the Patent Cooperation Treaty published as WO 00/20020 (referred to in the present decision as "the application as filed"). The refusal was based on the sole ground that claims 1 to 24 then on file did not meet the requirements of Article 123(2) EPC.
- II. On 5 September 2005, the appellant (applicant) filed a statement of grounds of appeal, which was accompanied by an amended main set of claims and five auxiliary sets of claims. Oral proceedings were requested in the event that the board should envisage dismissal of the appeal.
- III. The examining division did not rectify its decision and referred the appeal to the board of appeal under Article 109(2) EPC.
- IV. On 10 November 2006, oral proceedings took place, during which the appellant filed a new main request containing 8 claims which read as follows:
- "1. A method of screening agents for treatment of neurodegenerative disease comprising stimulating oxidative stress in neuronal cells, introducing the agent under evaluation for stimulation of expression of non-amyloidogenic protein and

testing for a decrease in the level of aggregation of NACP/ α -synuclein.

2. A method as claimed in claim 1 wherein oxidative stress is stimulated by a mixture of metal ions and hydrogen peroxide.
3. A method as claimed in claim 1 or claim 2 wherein the metal ions [*sic*] are selected from the group consisting of iron, aluminum, and copper.
4. A method is [*sic*] claimed in claim 1 wherein the non-amyloidogenic protein is β -synuclein.
5. A transgenic mouse comprising a heterologous nucleic acid comprising a human α -synuclein coding sequence, wherein the heterologous nucleic acid is operatively linked to a promoter capable of successfully targeting expression of human proteins in neurons in transgenic mice, and is integrated into the genome of the mouse.
6. The transgenic mouse of claim 5 where in [*sic*] the α -synuclein comprises α -synuclein non-amyloid component (NAC).
7. The transgenic mouse of claims 5 or 6 wherein the promoter is a PDGF β -promoter.
8. A transgenic mouse of any of claims 5 to 7 wherein the heterologous nucleic acid further comprises an SV40 intron."

- V. The appellant argued that basis under Article 123(2) EPC for the claimed subject-matter was found in the first paragraph of page 5, on page 13, line 27 to page 15, line 8, and on page 29, lines 9 to 14 of the application as filed.
- VI. The appellant requested that the decision under appeal be set aside and the case be remitted to the department of first instance for further prosecution on the basis of claims 1 to 8 of the new main request filed at the oral proceedings.

Reasons for the Decision

Article 123(2) EPC

1. The issue to be decided in these appeal proceedings is whether or not the subject-matter of claims 1 to 8 of the new main request filed at the oral proceedings is properly based on the application as filed, as required by Article 123(2) EPC.
2. Page 5, lines 4 to 10 of the application as filed refers to a method having all the features of the method according to claim 1. However, said passage states that oxidative stress in the neuronal cells is stimulated by introducing a mixture of metal-ions and hydrogen peroxide, whereas this feature is not stated in claim 1. When having regard to other parts of the application as filed, in particular original claim 4, the board considers that a skilled person would directly and unambiguously derive therefrom that oxidative stress may also be stimulated by means other

than a mixture of metal-ions and hydrogen peroxide. Consequently, the method of claim 1 is based on the application as filed.

3. The subject-matter of claims 2 and 3 finds a basis on page 5, lines 4 to 7. For the subject-matter of claim 4, a basis can be found on page 5, lines 10 to 11.

4. As concerns the subject-matter of claim 5, page 29, lines 10 to 14 as well as page 13, lines 27 to 31 refer to transgenic mice in which overexpression of human α -synuclein is directed by the PDGF β promoter. On page 14, lines 1 to 4, it is stated that "[t]he PDGF β promoter was chosen because it has been used successfully to target the expression of other human proteins to neurons in transgenic models of neurodegenerative disorders". The board takes the position that in view of this sentence, a skilled person would directly and unambiguously derive from the application as filed that promoters other than the PDGF β promoter may also be used, provided they show the same function, i.e. they are capable of successfully targeting the expression of the desired human α -synuclein in neurons of transgenic mice. Although said sentence of the application as filed refers to "transgenic models", the board is convinced that the skilled person would evidently and unambiguously consider mice as the predominant transgenic laboratory animal model. Furthermore, the skilled person would understand that the PDGF β promoter is only an example for a promoter which targets expression to neurons, and that the technical teaching of the application as filed is not limited to the use of said specific promoter. The board further considers that a skilled person would interpret the wording of

claim 5 such that the promoter referred to is capable of successfully targeting the expression of human α -synuclein in neurons of the claimed transgenic mouse. Therefore, claim 5 is properly based on the application as filed.

5. The subject-matter of claims 6 and 7 finds a basis on page 14, lines 5 to 9 and on page 13, lines 30 to 31, respectively. The subject-matter of claim 8 is based on page 14, line 15.
6. The board thus concludes that the claims of the new main request comply with the requirements of Article 123(2) EPC.
7. Since the application was refused for the sole reason that the claims before the examining division did not fulfil the requirements of Article 123(2) EPC, and no examination as to the other requirements of the EPC has yet taken place, the board exercises its discretionary power under Article 111(1) EPC to remit the case to the first instance for further prosecution. During that prosecution, the applicant should be given the opportunity to correct the three obvious errors still contained in claims 3, 4 and 6.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution on the basis of claims 1 to 8 of the new main request filed at the oral proceedings.

The Registrar:

Chair:

P. Cremona

U. M. Kinkeldey