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**Datasheet for the decision
of 12 November 2013**

Case Number: T 0194/10 - 3.3.04

Application Number: 01945896.7

Publication Number: 1309341

IPC: A61K 39/00, C07K 14/47,
A61P 25/28

Language of the proceedings: EN

Title of invention:
Prevention and treatment of Alzheimer's disease

Applicant:
Bioarctic Neuroscience AB

Headword:
Alzheimer's disease/BIOARCTIC NEUROSCIENCE

Relevant legal provisions:
EPC Art. 111(1)

Keyword:
"Auxiliary request 6 - remittal (yes)"

Decisions cited:
-

Catchword:
-



Case Number: T 0194/10 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 12 November 2013

Appellant: Bioarctic Neuroscience AB
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 11 September 2009
refusing European patent application
No. 01945896.7 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: C. Rennie-Smith
Members: B. Claes
M. Montrone

Summary of Facts and Submissions

- I. The appeal was lodged by the applicant (hereinafter "appellant") against the decision of the examining division to refuse European patent application 01945896.7 with the title "*Prevention and treatment of Alzheimer's disease*" which was published as international application WO 02/03911.
- II. The examining division decided at the oral proceedings held on 17 November 2008 that the subject-matter of the claims of a main request and auxiliary requests 1 to 3 before it did not comply with the requirements of Article 123(2) EPC. The subject-matter of at least claims 4 to 7 of auxiliary request 4 and claim 4 of auxiliary request 5 lacked inventive step (Article 56 EPC). In point 10 of its decision the examining division stated that it held an auxiliary request 6 to meet the requirements of the EPC. However, the applicant withdrew this request by a letter dated 29 May 2009 in response to a communication under Rule 71(3) EPC issued by the examining division after the oral proceedings.
- III. With the statement of grounds of appeal, the appellant filed a main request (identical to auxiliary request 4 before the examining division), an auxiliary request 1 (identical to auxiliary request 5 before the examining division and in which claims 4 to 6 of the main request were deleted) and an auxiliary request 2 (identical to the auxiliary request 6 filed before the examining division but which had later been withdrawn - see Section II above - and in which claims 4 to 7 of the main request were deleted). The appellant argued that

the subject-matter of the claims of these requests involved an inventive step.

- IV. The sole independent claim 1 of auxiliary request 2, filed with the statement of grounds of appeal read:

"1. A vaccine for prevention or treatment of Alzheimer's disease comprising a protofibril comprising an A β peptide wherein said A β peptide is selected from the group consisting of amino acids 1-39 of SEQ ID No. 1, amino acids 1-40 of SEQ ID No. 1 and amino acids 1-42 of SEQ ID No. 1."

Claims 2 and 3 were dependent on this claim.

- V. The appellant was summoned to oral proceedings to take place on 12 November 2013. In a subsequent communication pursuant to Article 15(1) RPBA and dated 24 September 2013, the appellant was informed of the preliminary, provisional and non-binding opinion of the board on certain pertinent issues to be dealt with at the oral proceedings. The board indicated that it was inclined to the same negative view as the examining division concerning inventive step of claims relating to the same subject-matter as claims 4 and 7 of the main request and claim 4 of auxiliary request 1. The board furthermore drew the appellant's attention to point 10 of the decision under appeal, wherein the examining division held that auxiliary request 6 (which was later withdrawn) met the requirements of the EPC (see section II, above) and informed the appellant that it conditionally envisaged setting aside the decision under appeal and remitting the case to the department of first instance with the order to grant a patent on

the basis of the claims of auxiliary request 2 and a description and figures to be adapted thereto.

- VI. With a letter dated 30 September 2013 the appellant filed two new auxiliary requests 1 and 2 and new auxiliary requests 3 and 4, the latter corresponding to the previously filed auxiliary requests 1 and 2 now being limited to amino acids 1-40 of SEQ ID No. 1.
- VII. The board received third party observations pursuant to Article 115 EPC dated 28 October 2013. The third party drew the board's attention to the appellant's post-published international patent application WO2005/123775. It was submitted that the applicant itself had in this application acknowledged that the present application does not provide the skilled person with sufficient information to produce protofibril-specific antibodies. Accordingly, to the extent that the claims related to protofibril-specific antibodies they were not enabled as admitted by the applicant and, to the extent that the claims related to antibodies having affinity to protofibril A β with cross-reactivity to monomer A β , they lacked an inventive step. In this context reference was also made to Ward *et al.* (2000), *Biochem. J.*, Vol. 345, pages 137-144. The observations concluded that no antibody or therapeutic use claim should be allowed.
- VIII. With a further letter dated 29 October 2013, the appellant responded to the board's communication and maintained its claim requests filed with its letter of 30 September 2013.

IX. With a letter dated 6 November 2013, the appellant reacted to the third party observations. The appellant filed further auxiliary requests and at the same time renumbered others. The previous auxiliary request 4 was now designated auxiliary request 6.

Claim 1 of auxiliary request 6 read:

"1. A vaccine for prevention or treatment of Alzheimer's disease comprising a protofibril comprising an A β peptide wherein said A β peptide consists of amino acids 1-40 of SEQ ID No. 1".

Claims 2 and 3 were dependent on this claim.

X. Oral proceedings took place on 12 November 2013. During the oral proceedings the appellant was heard on the issue of sufficiency of disclosure (Article 83 EPC) with regard to *inter alia* its later international patent application WO2005/123775 in respect of the invention as claimed in all the requests submitted with the appellant's letter of 6 November 2013. In the light of this discussion the appellant withdrew the main request and auxiliary requests 1 to 5. At the end of the oral proceedings the board gave its decision.

XI. The appellant requested that the decision under appeal be set aside and that auxiliary request 6 of 6 November 2013 be remitted to the department of first instance for further prosecution.

XII. The appellant's arguments, insofar as they are relevant for the present decision, can be summarised as follows:

Remittal to the department of first instance of auxiliary request 6

The issues raised in the third party observation dated 28 October 2013 relating to sufficiency of disclosure were only brought to the appellant's attention 2 weeks before the oral proceedings.

The third party observations only made statements relating to antibody claims and medical use claims and were silent on claims relating to vaccines.

Neither the examining division nor the board before the oral proceedings had informed the appellant that sufficiency of disclosure of the vaccine claims was of concern. In fact the board in its communication had indicated that it envisaged the order of the grant of a patent based on vaccine claims.

It was the opinion of the appellant that the statements in international patent application WO2005/123775 had no bearing on the sufficiency of vaccine claims limited to protofibrils based on A β peptide consisting of amino acids 1-40 of SEQ ID No. 1.

The concerns of the board expressed during the oral proceedings with respect to the sufficiency of disclosure of the patent application with the claims of auxiliary request 6 based on this document were therefore new to the appellant. They therefore merited the opportunity to have a decision on this issue in two

instances. Remittal of the case to the department of first instance was therefore appropriate.

Reasons for the Decision

1. The appeal is admissible.

Remittal to the department of first instance of auxiliary request 6

2. The appellant submitted (see section XII above) that the insufficiency issues arising from the third party observations of 28 October 2013 were only brought to its attention two weeks before the oral proceedings, that neither the examining division nor the board had prior to the oral proceedings informed the appellant that sufficiency of disclosure of the vaccine claims was of concern, and the board had in its communication indicated that it envisaged the grant of a patent based on those claims. These submissions were presented as "lateness" or "surprise" arguments why the board should exercise its discretion to remit the appellant's auxiliary request 6 to the examining division (Article 111(1) EPC).
3. Those arguments were *per se* factually correct but, unless seen in the context of the appellant's own conduct, misleading. The further fact underlying the late point in time at which the insufficiency issue was raised is that the appellant's later patent application WO2005/123775, which contains statements casting substantial doubt on the sufficiency of the disclosure of the patent application at issue in these proceedings,

was not known to the examining division when it made the decision under appeal and was not known to the board until it received the third party observations dated 28 October 2013. Only the appellant knew of the content of WO2005/123775 and only the appellant was, prior to 28 October 2013, in a position to appreciate the effect that application might have on the present case.

4. The board accepts that the appellant does not agree with the possible interpretation which can be placed on the statements in WO2005/123775 but the appellant - and until very recently only the appellant - was none the less able to see that those statements are potentially damaging to the present application. However, the appellant neither mentioned WO2005/123775 to the examining division at all nor considered its impact on the appeal proceedings until it was mentioned in the third party observations two weeks before the oral proceedings. Thus the lateness on which the appellant relies has arisen entirely from its own acts (making the damaging statements in WO2005/123775) and omissions (not disclosing those arguments previously). The board notes that the appellant did, during the oral proceedings on 12 November 2013, apologise for not addressing the issue earlier.

5. In the discussion during those oral proceedings of sufficiency of disclosure with reference to, in particular, the statements in WO2005/123775, the appellant argued that the claims directed to a vaccine could be distinguished on technical grounds from the other claims directed to an antibody and to the medical use of that antibody. While the board makes no comment

on that claimed distinction, it does note the appellant's further argument (see section XII above) that the third party observations which drew its attention to WO2005/123775 do not make any specific attack on the vaccine claims *per se*. The appellant's auxiliary request 6 contains only vaccine claims and these are the claims which the examining division was prepared to allow when the case was previously before it, although at that time the examining division did not know of the statements in WO2005/123775.

6. In all the circumstances of the case, the board accepts that the examining division should have the opportunity to re-appraise the claims it was previously prepared to allow in the light of the current state of the file and, in particular, in the light of the appellant's own statements about the current application in WO2005/123775.

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 auxiliary request 6 filed on 6 November 2013.

The Registrar:

The Chairman:

P. Cremona

C. Rennie-Smith