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D E C I S I O N
of 28 November 2005

Case Number: T 1303/04 - 3.3.04

Application Number: 98914725.1

Publication Number: 970121

IPC: C07K 14/47

Language of the proceedings: EN

Title of invention:
Peptide fragments of myelin basic protein, their pharmaceutical compositions and their use in treating multiple sclerosis

Applicant:
The Governors of the University of Alberta

Opponent:
-

Headword:
Myelin basic protein/UNIVERSITY OF ALBERTA

Relevant legal provisions:
EPC Art. 54, 111(1)

Keyword:
"Novelty (yes)"
"Remittal to the department of first instance (yes)"

Decisions cited:
G 0005/83, T 0464/94, T 1091/00

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1303/04 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 28 November 2005

Appellant: (Applicant)
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 18 June 2004 refusing European application No. 98914725.1 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: U. Kinkeldey
Members: M. Wieser
S. Perryman

Summary of Facts and Submissions

I. The appeal was lodged by the Applicants (Appellants) against the decision of the Examining Division to refuse under Article 97(1) EPC the patent application EP 98 914 725.1, international publication number WO 98/45 327. The patent application has the title: "Peptide fragments of myelin basic protein, their pharmaceutical compositions and their use in treating multiple sclerosis".

II. The following documents are referred to in this decision:

(1) WO 96/12 737

(2) WO 93/21 222

(3) WO 93/08 212

III. The Examining Division decided that claims 1 to 4, 6 and 7 of the only request before them did not meet the requirements of Article 54 EPC as their subject-matter was not novel over the disclosure in document (2). Moreover they decided that claim 5 did not involve an inventive step contrary to the requirements of Article 56 EPC in the light of the disclosure in document (2) in combination with document (3).

IV. The Appellants requested to set aside the decision under appeal, to acknowledge novelty (Article 54 EPC) of claims 1 to 7 filed on 23 April 2004 over the disclosure in the prior art documents on file and to

remit the case to the authority of first instance for further prosecution according to Article 111(1) EPC.

V. Claim 1 read as follows:

"The use of a peptide of the formula:

Asp Glu Asn Pro Val Val His Phe Phe Lys Asn Ile Val Thr Pro Arg Thr

in the manufacture of a medicament comprising the peptide as its only pharmaceutically active ingredient, which medicament is for use in the treatment of multiple sclerosis in a patient having an HLA-DR2 haplotype."

Dependent claims 2 to 7 referred to preferred embodiments of this use, whereby claim 5 related to intrathecal administration of the peptide.

Reasons for the decision

1. Document (2) is concerned with suppression of T-cell proliferation using peptide fragments of human myelin basic protein (hMBP). Several peptide fragments of hMBP are the subject of claim 1 of that document. One of these fragments, hMBP (84-100), is identical to the peptide referred to in claim 1 of the present patent application. Due to a different numbering of the amino acid residues, this peptide, in the present patent application, is designated MBP(82-98).

Claim 7 of document (2) refers to a method for suppressing immune function of $CD4^+$ T-cells reactive with MBP in a mammal afflicted with multiple sclerosis (MS), comprising administering to said mammal a peptide comprising an immunodominant epitope of MBP. Claim 9 of document (2) discloses a pharmaceutical composition comprising such peptide. According to page 17, line 35 to page 18, line 2, the immunodominant epitope has been localized within hMBP amino acids Nos. 85-99.

2. Claim 1 of the present application is drawn up in the conventional "second (or further) medical use" format. According to the decision of the Enlarged Board of Appeal G 5/83 (OJ EPO 1985, 64), novelty and inventive step of such claims can be derived from their sole new feature, that is the new pharmaceutical use of a known substance.

This pharmaceutical use is defined as being "...the treatment of multiple sclerosis in a patient having an HLA-DR2 haplotype."

3. In point (2) of the decision under appeal the Examining Division correctly pointed out, that, in order to decide the issue of novelty of claim 1, it has to answered whether document (2) discloses the use of hMBP(84-100) for treatment of multiple sclerosis in patients having an HLA-DR2 haplotype.

4. Example 7 of document (2) demonstrates that hMBP(84-102), which is distinguished from the peptide referred to in present claim 1 by two additional Proline residues at the C-terminal end, associates with the HLA-DR2 haplotype (see page 59, lines 13 to 15).

5. The Examining Division drew the following conclusions from the disclosure in document (2):

5.1 It was the central teaching of the document that fragments of hMBP embodying the immunodominant epitope (amino acid Nos. 85-99) could be used to suppress the autoimmune response of T cells. Therefore, all peptides disclosed in claim 1 of document (2) were equivalents, presenting the same immunodominant epitope and thus affecting the epitope dependent T-cells in the same way (point (3) of the decision under appeal).

5.2 As the immunodominant epitope encompassed by hMBP(84-102) is associated with the T-cells of the HLA-DR2 haplotype, also other peptides mentioned in claim 1 of document (2) and encompassing said immunodominant epitope would associate with T-cells of this haplotype.

The teaching of document (2) would guide a skilled person inevitably to use peptides embodying the immunodominant epitope of hMBP, such as the peptide referred to in present claim 1, in the treatment of MS in patients having an HLA-DR2 haplotype (point (4) of the decision under appeal).

5.3 Although the Examining Division accepted that hMBP(84-102) and hMBP(84-100) were different peptides having different properties, they stated that for the issue of novelty in the present case only those properties of the peptides were relevant which defined their immunological activity. This activity was related to the immunodominant epitope only, which was identically contained in both peptides. Minor

amendments at the N- and/or C-terminus of the peptides were not considered to affect their immunological activity towards T-cells specific for the epitope (point (6) of the decision).

5.4 The absence of a specific example in document (2), disclosing the use of hMBP(84-100) in the treatment of MS patients having an HLA-DR2 haplotype, was not considered to be critical. On the contrary, the Examining Division stated, that *"[I]n order to acknowledge novelty to not specifically disclosed subject-matter it is considered to be necessary that said subject-matter is based on a new technical teaching."* It was found not to be **plausible** that the use of hMBP(84-100) differed essentially from the use of hMBP(84-102) and would result in an **unexpected advantageous effect** (see point (7) of the decision under appeal).

5.5 The Examining Division concluded that the subject-matter of claim 1 of the present patent application was not novel over the disclosure in document (2).

The same decision was reached with regard to dependent claims 2 to 4, 6 and 7, whose features all were considered to be explicitly disclosed in document (2).

6. In the Board's view it is not justifiable to decide whether a document is prejudicial to novelty on the **basis of probability or plausibility**. In order to decide that the subject-matter of a claim lacks novelty, the department concerned, having taken all facts and arguments put forward during the proceedings into consideration, has to be **sure** that the decision is

justified (cf decision T 464/94 of 21 May 1997; point (16) of the reasons).

In the present case, although there might be some probability that hMBP(84-100) has the same or similar immunological activity as hMBP(84-102), there is no convincing evidence on file that would allow arriving at this solution with certainty. On the contrary, document (2), in Example 3 and figure 8 demonstrates that slightly different hMBP peptides give different results with regard to their ability to stimulate proliferation of hMBP-reactive T-cell clones.

7. Accordingly, in the light of the relevant case law of the Boards of Appeal, document (2) does not anticipate the subject-matter of claims 1 to 4, 6 and 7 of the present patent application.

8. Document (1), providing isolated peptides and combinations of peptides derived from MBP for treating MS, discloses in figure 14 the peptide referred to in present claim 1. The document refers to patients having an HLA-DR2 haplotype in Example 1 only. This example, starting on page 39 of document (1), reports on a human population study of MS immune response to MBP peptides and the selection of MBP peptides suitable for therapeutic use. The MBP peptides used in these studies are shown in figure 3. The figure does not disclose the peptide referred to in present claim 1. In the sentence bridging pages 40 and 41 it is said *"...that both DR2 and non-DR2 MS patients have good reactivity to* ***these peptides"*** (emphasis added by the Board). The term **"these peptides"** refers to MBP(81-100) and MBP(83-105), which in the foregoing sentence are said to correspond

to a region previously thought to be associated with the HLA-DR2 haplotype.

9. Document (3), also referring to methods and compositions comprising peptide fragments of hMBP for treatment of MS, does not disclose the peptide referred to in present claim 1.

10. Therefore, the subject-matter of claim 1 and of claims 2 to 7 dependent thereon is not anticipated by the disclosure in documents (1) and (3) and meets the requirements of Article 54 EPC.

11. According to Article 111(1) EPC the Board of Appeal may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to the department for further prosecution.

Remittal to the department of first instance is at the discretion of the board (cf decision T 1091/00, 2 July 2002).

Although Article 111(1) EPC does not guarantee an absolute right to have all the issues in the case considered by two instances, it is well recognised that a party should preferably be given the opportunity to have two instances consider the important elements of its case. The essential function of appeal proceedings is to consider whether the decision which has been issued by the first instance department is correct. Hence, a case is normally remitted, if essential questions regarding the patentability of the claimed

subject-matter have not yet been examined and decided by the department of first instance.

In particular, remittal is taken into consideration by the boards in cases where a first instance department issues a decision solely upon one particular issue which is decisive for the case against a party and leaves other essential issues outstanding. If, following appeal proceedings, the appeal on the particular issue is allowed, the case is normally remitted to the first instance department for consideration of the undecided issues.

12. The Examining Division in the decision under appeal has only dealt with the question of novelty in relation to document (2), without comprehensively touching any other substantial requirements of the EPC.

The Board notes that the Examining Division has not decided whether or not the claims involve an inventive step according to the requirements of Article 56 EPC, except in relation to claim 5, for which the way of administering the peptide intrathecally was acknowledged as novel but considered as an obvious solution to the problem of finding an alternative way of administering such peptide. The Examining Division in the present case did not consider what the problem to be solved might be if claim 1 was acknowledged as novel.

13. Thus, a fundamental requirement for the grant of a patent has not yet been examined by the first instance. Consequently, the examination was not carried out in a way to put the Board in a position to decide now,

assisted by a comprehensive examination of all the issues by the first instance, whether or not the substantial requirements of the EPC are met by the present patent application, which, considering the economical aspect of the procedure, would be the most preferred situation.

Therefore, although being aware that this could lead to a considerable delay of the procedure, the Board considers it to be justified and appropriate to allow the present set of claims to be examined by two instances, and therefore exercises its discretion under Article 111(1) EPC to remit the case to the first instance for further prosecution.

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 7 filed on 23 April 2004.

Registrar: Chair:

P. Cremona U. Kinkeldey