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**D E C I S I O N**  
of 14 November 1997

**Case Number:** W 0003/97 - 3.3.4

**Application Number:** PCT/US 95/13682

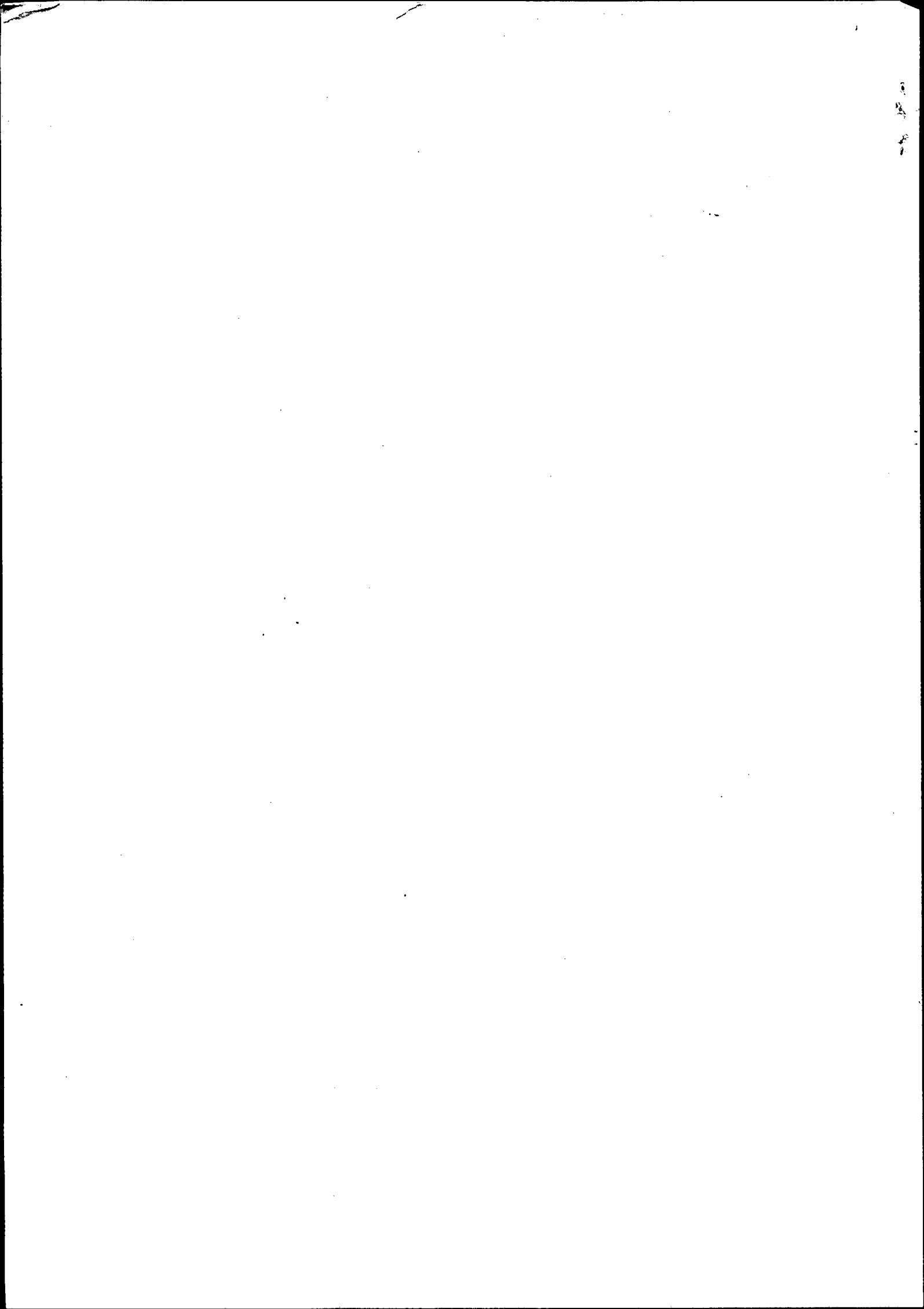
**Language of the proceedings:** EN

**Applicant:**  
Immulogic Pharmaceutical Corp. et al

**Opponent:**  
-

**Headword:**  
-

**Relevant legal provisions:**  
PCT Art. 34(3)(a)  
PCT R. 68.3(c) and 13.1





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Case Number: W 0003/97 - 3.3.4  
International Application No. PCT/US 95/13682

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.4  
of 14 November 1997

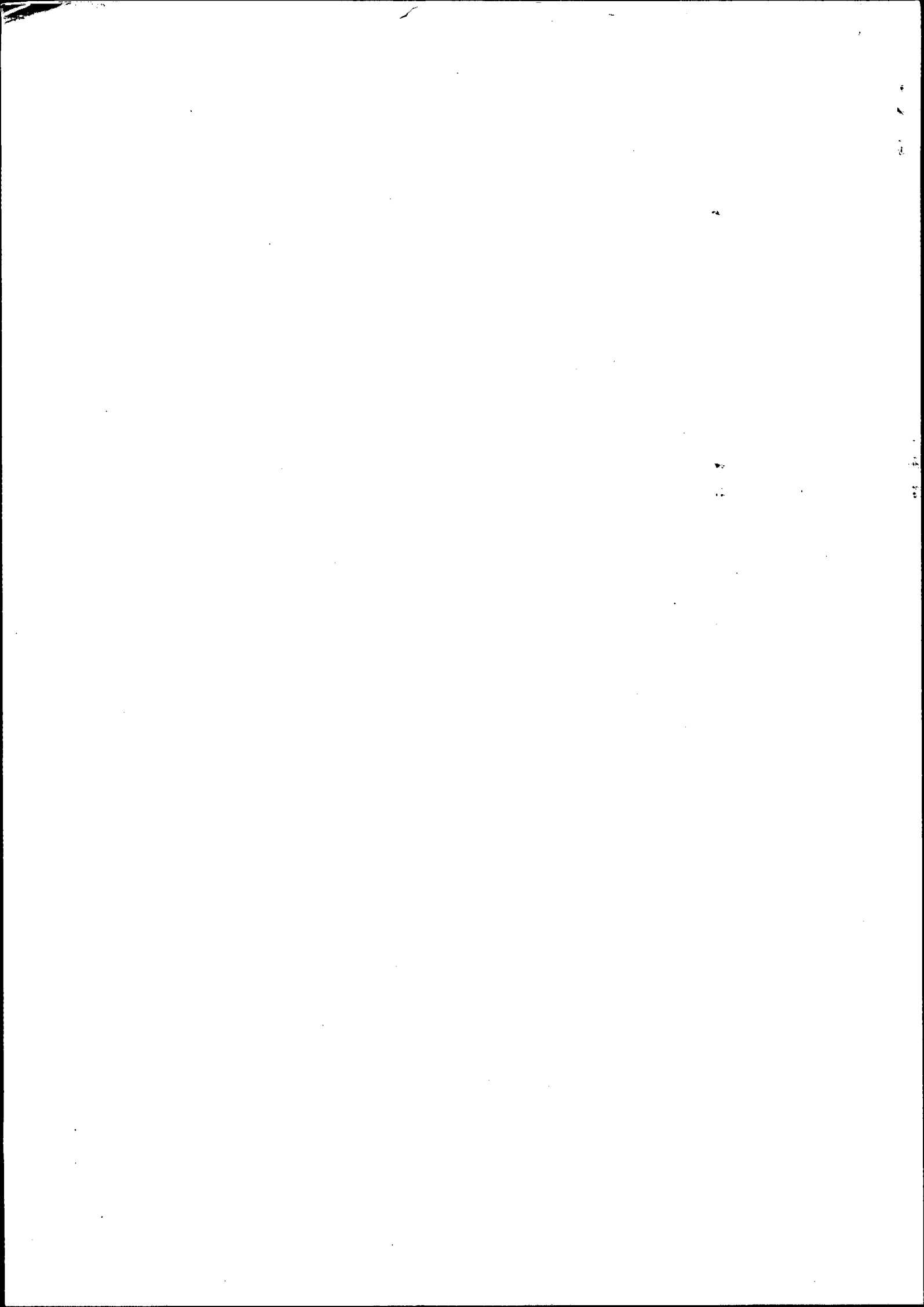
**Applicant:** Immulogic Pharmaceutical Corp. et al  
610 Lincoln Street  
Waltham, MA 02154 (US)

**Representative:** Anne I. Craig  
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**Subject of the Decision:** Protest according to Rule 68.3(c) of the Patent  
Cooperation Treaty made by the applicant  
against the invitation (payment of additional  
fee) of the European Patent Office  
(International Preliminary Examining Authority)  
dated 24 September 1996.

**Composition of the Board:**

**Chairman:** U. M. Kinkeldey  
**Members:** L. Galligani  
R. Teschemacher



## Summary of Facts and Submissions

I. International patent application PCT/US 95/13682 was filed on 25 October 1995 with seventy-four claims of which claims 1, 18 to 19 and 21 to 22 read as follows:

"1. A composition for treating multiple sclerosis in a mammal comprising at least one peptide, said peptide selected from the following group of peptides: MBP-1, MBP-1.1, MBP-1.2, MBP-2, MBP-2.1, MBP-2.2, MBP-2.3, MBP-2.4, MBP-2.5, MBP-2.6, MBP-3, MBP-3.1, MBP-4 and MBP-5 all as shown in Fig.2, or modifications or analogs or peptidomimetics thereof.

18. An isolated peptide derived from MBP wherein said peptide is selected from the group consisting of: MBP-1.1, MBP-1.2, MBP-2.1, MBP-2.2, MBP-2.3, MBP-2.4, MBP-2.5, MBP-2.6, MBP-3.1, MBP-4, and MBP-5 all as shown in Fig.2, or a modification or analogs thereof.

19. An isolated peptide of claim 18 wherein said peptide is MBP-4 or modification or analog thereof.

21. A peptide selected from the group consisting of MBP-2, MBP-2.1, MBP-2.2, MBP-2.3, MBP-2.4, MBP-2.5, MBP-2.6 all as shown in Fig.2, wherein lysine (K) is substituted with alanine (A).

22. A peptide analog of MBP-2.1 wherein lysine (K) at position 10 is substituted with alanine (A), said peptide analog having the amino acid sequence DENPVVHFFANIVTPRTPPPSQGK."

II. On 24 September 1996 the European Patent Office (EPO), acting as an International Preliminary Examining Authority (IPEA), invited the applicants to pay within a time limit of one month **five** additional examination

fees pursuant to Article 34(3)(a) and Rule 68.2 PCT. Reference was made to the reasons given in communication dated 3 May 1996 of the EPO, acting as International Searching Authority (ISA), according to which the application related to the following groups of inventions which were not linked by a single inventive concept:

1. Claims 1 to 18, 20, 23 to 74 (all partially);
2. Claims 1 to 18, 20, 23 to 74 (all partially) and claims 19, 21, 22 (all completely);
3. Claims 5, 14 to 17, 30, 32, 33, 37 to 42, 44 to 51, 53 to 59, 62, 64, 66, 67, 70, 74 (all partially);
4. Claims 37 to 41, 44, 46 to 50, 55 to 59, 62 (all partially)
5. Claims 37 to 41, 44, 46 to 50, 55 to 59, 62 (all partially);
6. Claims 37 to 41, 44, 46 to 50, 55 to 60, 62 (all partially).

The ISA had therein observed that, firstly, solutions to the problem of providing a myelin antigen per se and its use in the treatment of multiple sclerosis were known in the prior art, for example, from the following document:

- (1) WO-A-93/21222.

Secondly, there were essential differences between the different peptide fragments proposed as solution to the problem of providing alternative peptide antigens so that there was no single inventive concept underlying the plurality of claimed inventions.

IV. On 21 October 1996, the applicants paid **three** additional fees in respect of the additional inventions of groups 2, 3 and 6. Of these, the fee in respect of group 2 was paid under protest. In the applicants' view, the inventions of group 1 and 2 had the technical relationship necessary to satisfy unity of invention as both groups related to peptides of the myelin basic protein (MBP), derivatives thereof, and compositions containing such peptides. In the applicants' submission, although the peptides derive from different regions of the MBP protein, no burden is placed on the IPEA in establishing the report.

V. On 18 November 1996, the IPEA issued a communication informing the applicants that, after a prior review of the justification for the invitation to pay additional fees, the requirement of payment thereof was upheld. The applicants were thus invited under Rule 68.3(e) PCT to pay the protest fee. The IPEA considered that, having regard to document (1) as well as to a whole series of other prior art documents concerned with peptides of the N-terminal or C-terminal half of MBP, it was justified to deny a unitary link between the peptides of group 1 and those of group 2.

VI. The protest fee was paid by the applicants on 25 November 1996.

## Reasons for the Decision

1. The protest in respect of the payment of a further examination fee is admissible.
  
2. According to the PCT Regulations (cf. Rule 13.1 PCT), the international patent application shall relate to one invention only or to a group of inventions so linked as to form a single inventive concept. The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim (cf. Rule 13.3 PCT).
  
3. The Board has to examine whether the claims of group 1 and group 2 (see Section II above) fulfil the requirements of unity. Claim 1 at issue relates to several alternative compositions for treating multiple sclerosis, these being in relation to the particular peptide which is selected as the active ingredient. The IPEA has considered that a group of these alternative compositions, namely the compositions comprising the peptides MBP-1, MBP-1.1, MBP-1.2 which are derived from the N-terminal half of MBP, constitutes an invention (group 1) which is not linked to the group of the remaining alternatives (group 2), ie the composition comprising the peptides MBP-2, MBP-2.1, MBP-2.2, MBP-2.3, MBP-2.4, MBP-2.5, MBP-2.6, MBP-3, MBP-3.1, MBP-4, MBP-5 which are derived from the C-terminal half of MBP, so as to form a single general inventive concept as set forth in the PCT regulations. Consequently, the IPEA classified claim 1 as well as other claims

referring to all the quoted peptides (eg claim 18) partially under group 1 and partially under group 2. On the other hand, claims 19, 21, 22, which are only concerned with peptides derived from the C-terminal half of MBP, were classified under group 2.

4. The amino acid sequence of mammalian MBP, in particular of human MBP, was known in the art (cf. document (1)). Furthermore, compositions for treating multiple sclerosis comprising at least one peptide corresponding to an epitope of MBP either from the C-terminal or N-terminal domain of MBP were also known in the art. In this respect, the IPEA has provided several citations. The already quoted document (1), for example, describes compositions based on peptides containing the immunodominant epitope which is located at the C-terminal end. The following two documents, among the many others referred to,

(4) WO-A-88/10120, and

(5) J.Neuroimmunol., Vol. 31, 1991, pages 105 to 113

refer to compositions based on peptides corresponding to epitopes located at the N-terminal end.

5. In the light of the cited prior art, each successive identification of peptide fragments corresponding to an epitope of mammalian MBP to be used in a composition for treating multiple sclerosis constitutes a separate solution to the separate - although analogous - technical problems of finding further epitopes of the said autoantigen associated with this disease condition. In particular, peptides derived from different regions of the known molecule, as here those of group 1 derived from the N-terminal domain and those of group 2 derived from the C-terminal domain, have different primary structures and different antigenic

implications. The common use, ie their use in a composition for treating multiple sclerosis, does not constitute a "special technical feature" in the sense set out in Rule 13.2 PCT which could provide a unitary link because this was the known purpose of the prior art peptides and compositions as well.

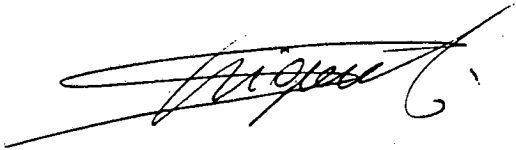
6. For the foregoing reasons, the Board sees no such "special technical feature" which links groups 1 and 2 of inventions. Thus, the invitation made under Article 34(3)(a) and Rule 68.2 PCT to pay the additional fee was justified.
  
7. As for the argument put forward by the applicants that "no burden is placed on the IPEA in establishing the report", the board has no reasons whatsoever to believe that the IPEA abused of its authority in inviting the applicants under Rule 68 PCT to either restrict the claims or pay additional fees. It is observed that a large proportion (18 out of 23) of the documents quoted in the international search report of 30 July 1996 as being relevant in relation to inter alia claims 19, 21, 22, which are specific to group 2, had not been cited in the partial international search report established for group 1. This difference is prima facie indicative of an additional burden placed on the IPEA in establishing the report.

**Order**

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

The protest according to Rule 68.3(c) PCT is dismissed.

The Registrar:



D. Spigarelli

The Chairperson:



U. M. Kinkeldey

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