BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

A		B	X	C	

File No.: T 0065/92 - 3.3.2

Application No.: 84 901 861.9

Publication No.: 0 151 579

Classification: C12N 7/06

Title of invention: Method and products for detection of human T cell leukemia virus

D E C I S I O N
of 13 June 1993

Applicant: THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE

Proprietor of the patent:

Opponent:

Headword: HTLV/HARVARD COLLEGE

EPC: Art. 87

Keyword: "Right to priority (yes); disclosure of same invention"

Headnote
Catchwords

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0065/92 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 13 June 1993

Appellant: THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE
17 Quincy Street
Cambridge, MA 02138 (US)

Representative: Moon, Donald Keith
BREWER & SON
Quality House
Quality Court
Chancery Lane
London WC2A 1HT (GB)

Decision under appeal: **Decision of the Examining Division of the European Patent Office dated 31 July 1991 refusing European patent application No. 84 901 861.9 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: P.A.M. Lançon
Members: L. Galligani
E.M.C. Holtz

Summary of Facts and Submissions

I. European patent application No. 84 901 861.9 filed on 13 April 1984 and published as an International patent application under No. WO 84/04327, claiming the priority from the US application No. 489 187 filed on 27 April 1983, was refused by the Examining Division on 31 July 1991.

The decision was taken on the basis of amended Claims 1 to 6, 8 to 18, 20 to 29 and 31 to 32 filed by letter of 31 July 1990 (original Claims 7, 19 and 30 being deleted).

Claim 1 reads as follows:

" A substantially pure polypeptide having an antigenic determinant or determinants immunologically cross-reactive with the determinants of a glycoprotein having a molecular weight of approximately 61,000-68,000 daltons, of which approximately 46-48,000 daltons is the molecular weight of the unglycosylated moiety, said glycoprotein being present on the cell surface of cells infected with the human T-cell leukemia virus."

II. The Examining Division refused the application under Article 97(1) EPC because it considered that, since Claim 1 could not derive a valid priority from US 489 187, its subject-matter lacked novelty within the meaning of Article 54 EPC having regard to the following publications:

(a) Yamamoto et al., Int.J.Cancer, 1983, Vol. 32, pp. 281-287 (referred to as "Yamamoto II");

(b) Hattori et al., Gann, 1983, Vol. 74, pp. 790-793 (referred to as "Hattori");

(c) Essex et al., Science, 1983, Vol. 220, pp. 859-861 (referred to as "Essex").

The Examining Division pointed out that the upper molecular weight limit of 68,000 daltons (68kD) constituted an essential technical feature of the glycosylated polypeptide referred to in Claim 1. In the priority document said upper limit was consistently indicated as 65,000 daltons (65kD). Although admitting that the skilled person after reading the two documents (priority and present application) would have suspected the two polypeptides to be identical, the Examining Division maintained that such an "understanding" could not be sufficient to establish a right of priority according to Article 87 EPC also in the light of the decision T 81/87 (OJ EPO, 1990, 250). The Examining Division, therefore, concluded that claim 1 was not entitled to the priority date and that, consequently, it lacked novelty *vis-à-vis* documents (a) to (c) which described a HTLV-associated cell surface glycoprotein with a molecular weight falling within the given range.

III. The Appellant lodged an appeal against this decision and paid the appeal fee.

The Appellant essentially argued that the technical feature of the molecular weight of the claimed glycoprotein should have been given the same interpretation as that which it would have been given by the skilled person. A difference of 3kD between the reported molecular weight of the subject glycoprotein in the application and in the priority document would not have given her/him any reason to doubt about their being identical because:

(i) it was known that the measurement of molecular weight had an inherent degree of inaccuracy;

(ii) an identical protocol for the preparation of the glycoprotein was given in the two documents;

(iii) both the application and the priority document clearly stated that the molecular weight could be slightly variable.

Under these circumstances, priority should have been considered valid. Consequently the novelty objection did not apply.

IV. The Appellant requests the setting aside of the decision of the Examining Division.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments (Article 123(2) EPC)*

There are no objections under Article 123(2) to the set of claims filed by letter of 31 July 1990 as the amendments with respect to the application as originally filed consist in the deletion of the smaller glycoprotein.

3. *Priority (Article 87 EPC)*

The question at issue is whether the subject-matter of Claim 1 is entitled to the priority date. If not, documents (a) to (c) cited by the Examining Division would constitute state of the art within the meaning of Article 54(2) EPC and could affect the novelty of Claim 1.

3.1 The right to priority is governed by Article 87 EPC which requires that the European patent application and the application whose priority is claimed relate to the **same invention**, i.e. to the same subject-matter. Thus, the main criterion in this respect is whether the claimed invention is disclosed in the priority document as a matter of substance, i.e. with all its essential features. According to decision T 81/87, which was cited by the Examining Division, the disclosure of the essential elements "must be either express, or be directly and unambiguously implied by the text. Missing elements which are to be recognized as essential only later on are thus not part of the disclosure". This view was confirmed also *inter alia* in decision T 301/87 (OJ EPO, 1990, 335).

3.2 In the present case, the experimental protocols given in the application and in the priority document for the preparation and characterisation of the subject polypeptide are word for word identical (compare Example 1 in the two documents). The said polypeptide is isolated **by the same method** and **from the same source**. Moreover, its characterisation is carried out **by the same method** (SDS-PAGE) **under the same experimental conditions**. Thus, the intended final product must be the same in the two documents.

However, while the priority document indicates for the glycosylated form of the polypeptide a molecular weight range of 61 to **65** kD, the present application indicates a range of 61 to **68** kD (the different upper limits have been emphasised).

The molecular weight range for the unglycosylated form of the polypeptide is **identical** in the two documents, i.e. 46 to 48 kD.

The present application (see page 5, lines 17 to 21) and the priority document (see page 5, lines 20 to 24) state that "the unglycosylated moiety ... contains substantially the same antigenic determinant or determinants as does the glycoprotein itself". This seems to imply that said difference is at least qualitatively irrelevant with respect to the antigenic function of the protein because said function is associated with the unglycosylated core.

3.3 As regards the reported molecular weight values, they are admittedly approximate values. Slight variations around said limits without a change in the functional properties of the protein are, therefore, plausible. This is recognised both in the present application (see page 5, last paragraph) and in the priority document (see page 5, last paragraph) where, by use of the same wording, it is stated that "the exact sizes of the novel glycoproteins are slightly different in different lines; however, the common immunologically cross-reactive portion of the glycoproteins is the same regardless of cell line, since it is a protein induced by HTLV". Moreover, it is well known that molecular weight determinations by SDS-PAGE are per se not very precise. This has been confirmed in the written submissions by the Appellant (see especially the affidavit dated 26 November 1991 by Dr P.J. Fischinger). The molecular weight of migrated discrete protein bands is calculated with respect to the migration of known reference standards. Many factors can influence the migration of proteins in a gel (nature of the protein, sieving properties of the gel etc.). Therefore, the lower and upper limits of a molecular weight range as determined by SDS-PAGE are generally regarded as approximate, not as exact values.

The difference in the upper limit of the molecular weight of the glycosylated form could also well be considered to fall within the experimental error when running gel electrophoresis.

3.4 Given the facts depicted above, there is nothing on file which leads the Board to believe that the reported difference originates from a true structural difference between the product of the present application and that of the priority document or from an attempt by the Appellant to cover - through the change of the upper limit from 65kD to 68kD - elements which have been recognised as essential only later.

3.5 All the essential features and elements which characterise the polypeptide of the present application are also disclosed in the priority document. These are the source of the polypeptide, the method for its preparation, the immunological reactivity, the approximate molecular weight of the unglycosylated and glycosylated forms.

3.6 In the Board's view, in the light of what has been stated above, the difference in the reported upper limit of the molecular weight range for the glycosylated form is not of such relevance as to bring to the conclusion that the present application and the priority document do not relate to the same invention. It seems quite clear that a skilled person would interpret the two documents as relating in substance to the same subject-matter.

3.7 In conclusion, the particular circumstances of the present case justify the recognition of the priority right under Article 87 EPC to the subject-matter of Claim 1 because the same matter is disclosed in substance in the priority document.

In view of the provisions of Article 89 EPC, documents (a) to (c) cited by the Examining Division cannot be considered as state of the art within the meaning of Article 54(2) EPC.

The examination as to novelty and inventive step with respect to other possible prior art documents will have to be carried out accordingly. The case is therefore remitted to the Examining Division for further prosecution under Article 111 EPC.

4. *Further matters*

In the course of the further prosecution of the case, the Examining Division should consider whether, for clarity purposes, the molecular weight data should be accompanied in the claims by a reference to the method used for its determination.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Examining Division for further prosecution.

The Registrar: The Chairman:

P. Martorana P.A.M. Lançon