BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS | BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE | CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Publication in the Official Journal ~~Yes~~ / No

File Number: T 365/88 - 3.3.2

Application No.: 81 301 413.1

Publication No.: 0 041 767

Title of invention: Improved vectors and methods for making such vectors and for expressing cloned genes

Classification: C12N 15/00

D E C I S I O N
of 5 August 1991

Applicant: Biogen, Inc.

Headword: Improved vectors/BIOGEN

EPC Article 123(2) and Rule 88

Keyword: "Allowability of amendments and corrections - (yes)"

Headnote

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number : T 365/88 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 5 August 1991

Appellant : Biogen, Inc.
Fourteen Cambridge Center
Cambrdige, Massachusetts 02142 (US)

Representative : Bannermann, David Gardner
Withers & Rogers
4 Dyer's Buildings
Holborn
London EC1N 2JT (GB)

Decision under appeal : Decision of Examining Division of the European Patent Office dated 26.10.1987 refusing European patent application No. 81 301 413.1 pursuant to Article 97(1) EPC.

Composition of the Board :

Chairman : P.A.M. Lançon
Members : U.M. Kinkeldey
R.L.J. Schulte

Summary of Facts and Submissions

I. European patent application No. 81 301 413.1 was filed with seventeen claims. Originally filed Claim 1 reads as follows:

"1. A vector comprising at least one DNA sequence comprising at least one promoter and operator derived from bacteriophage λ, characterised by at least one endonuclease recognition site located less than about 300 base pairs from that portion of the said DNA sequence comprising said promoter and operator."

II. The Examining Division refused the patent application on the grounds that Claim 1 filed during the examination procedure did not meet the requirements of Article 123(2) EPC. The claim reads as follows (amendments compared to the originally filed Claim 1 emphasised by the Board):

"1. A plasmid vector comprising at least one DNA sequence comprising the leftward promoter and operator derived from bacteriophage λ , P_LO_L, said DNA sequence being characterised by the absence of an active cro gene and an active N gene, and by at least one endonuclease recognition site located less than 300 base pairs downstream from P_LO_L and located between P_LO_L and any coding region of an N gene in said DNA sequence."

Independent method Claim 7 was amended in an analogous way as Claim 1.

The Examining Division based its rejection of the application on the reasons that the amendment in Claim 1 was the arbitrary selection of features which had not been disclosed alone or in combination with the other features

of the vectors and thus this selection was novel in the absence of a specific disclosure identifying or implying the same. A feature in question was that an endonuclease recognition site was located between P_LO_L and "any coding region of an N gene in said DNA sequence".

In an "Annex" to the impugned decision, the Examining Division also already provided comments relevant to Claims 7 and 15, whose subject-matter was also said not to be allowable under Article 123(2) EPC.

III. a) The Appellants lodged an appeal against this decision, paid the appeal fees and filed a Statement of Grounds of Appeal.

Together with the Statement of Grounds new claims were submitted, which were, in response to a communication issued by the Board, finally replaced by a set of claims filed with a letter on 2 April 1990, Claim 1 of which reads as follows (amendments compared to Claim 1 as originally filed emphasised by the Board):

"1. A plasmid vector comprising at least one DNA sequence comprising the leftward promoter and operator derived from bacteriophage λ, P_LO_L, said DNA sequence being characterized by the absence of an active cro gene and an active N gene and by at least one endonuclease recognition site located less than 300 base pairs downstream from P_LO_L in said DNA sequence."

Independent method Claims 7 and 12 were worded in an analogous way to above cited Claim 1.

In new Claims 2 and 8 amendments as to the abreviations of restriction enzymes were requested. "Xba" was to be replaced by "XbaI"; "Sal" was to be replaced by "SalI".

Claims 3 and 9 were worded such that "said recognition site is located less than about 150 base pairs downstream from P_LO_L in said DNA sequence".

New Claim 15 refers to eleven plasmid vectors deposited with two acknowledged depositary institution and are defined by their deposition numbers.

b) In a final set of claims filed for Austria with letter of 17 July 1991 the claims have been amended in a corresponding way.

c) Together with the grounds of appeal a new page 19 of the description was filed requesting amendment of the number "73.3%" into "73.1%".

d) As to the allowability of the amended claims, the Appellants submitted in essence that the feature that the endonuclease recognition site was located less than 300 base pairs downstream from P_LO_L was to be found in the specification as originally filed on page 6, lines 10 to 16. The characterisation of the endonuclease recognition site as being located less than 300 base pairs downstream of P_LO_L was necessary to define the invention. The same amendment had been carried out in Claims 7 and 12, which were thus equally allowable.

The feature that the respective recognition site is based 150 base pairs downstream from the P_L promoter as now contained in Claims 3 and 9, was disclosed in the specification at page 16, line 34, at page 17, line 3 and in Figure 2 in the plasmid pPLa23. The art was taught at pages 14 to 29 of the originally filed application, how to construct numerous plasmid vectors that necessarily embodied the feature specified by the amended claims, for example the constructions of plasmids pPLa23, pPLa2311, pPLa831 and pPLc236. Thus, several examples were provided wherein the endonuclease recognition sites were located less than 300 base pairs, e.g. 150 base pairs, downstream from P_LO_L in the DNA sequence of the claimed plasmid vector. It was not necessary to specifically exemplify a plasmid vector having an endonuclease recognition site for each and every distance less than 300 base pairs downstream from P_LO_L in order to comply with Article 123(2) EPC, since the capability of constructing an endonuclease recognition site at a desired point in the DNA sequence in relation to P_LO_L was within the skill of persons familiar with the respective technology.

e) Corrections of Claims 2 and 8 were allowable because the abreviation "SalI" was disclosed on page 40 and in Figure 4 of the description; "XbaI" was implicitly disclosed since there was only one type of such restriction enzyme known at the priority date. The addition of the Roman number "I" was for clarity purposes as confusion with later purified enzymes of that type was avoided.

IV. The Appellants request that the decision be set aside and that a European patent be granted on the basis of the claims on file.

Reasons for the Decision

1. The appeal is admissible.

2. The issue to be dealt with is the allowability of the amended claims under Article 123(2) and Rule 88 EPC.

The claims which now form the basis for the appeal procedure differ from those claims which formed the basis for the decision of the Examining Division such that the reasons for the refusal of the latter claims are no longer relevant.

2.1 Amendments (Article 123(2) EPC)

2.1.1 The differences of Claim 1 now on file to the originally filed Claim 1 are:

- The leftward promoter and operator, called P_LO_L, is used;

- the DNA sequence is characterised by the absence of an active cro gene and an active N gene; and

- that the recognition site is located less than 300 base pairs downstream from P_LO_L in said DNA sequence.

2.1.2 The feature that the used promoter and operator region is the "leftward" one becomes clear from the detailed description and figures which only make use of the "P_LO_L" promoter-operator region; this becomes apparent from the abbreviation for all plasmids constructed according to the detailed description, namely pP_L ... . The use of leftward promoter is further mentioned expressis verbis on page 12, lines 18 to 31. From the wording of this part of the description it is abundantly clear that a plasmid vector

was prepared containing the structure of the P_LO_L region, i.e. the leftward promoter and operator region of the bacteriophage λ.

A further disclosure of this feature was given in originally filed Claim 3 which described a vector comprising a promoter and operator being either P_LO_L or P_RO_R.

Incorporating the discussed feature into the claims, therefore, meets the requirements of Article 123(2) EPC.

2.1.3 The further additional feature in the main claim now on file, that a certain DNA sequence is characterised by the absence of an active cro gene and an active N gene, finds its support for example in originally filed Claim 2, the subject-matter of Claim 2 being now incorporated into Claim 1. Support can be found in the description as originally filed on page 6, lines 26 to 28.

There are, thus, no objections as to this feature with regard to Article 123(2) EPC.

2.1.4 Finally, there is now the feature in Claim 1 that at least one endonuclease recognition site is located less than 300 base pairs downstream from P_LO_L in said DNA sequence.

The preparation of a specific plasmid, namely pPLa23, is described on pages 16 to 20 of the originally filed documents, in which part it is originally disclosed that the "introduction of an EcoRI site at a short distance downstream from P_L" is to be carried out. At pages 20 to 29 of the original disclosure and corresponding Figures 3 and 4, it is also described that endonuclease recognition sites may be placed a short distance downstream from P_LO_L and between P_LO_L and any coding region of an N gene.

This feature thus is also described in the application as originally filed.

2.1.5 Claims 3 and 9 now on file contain the feature that the recognition site is located less than about 150 base pairs downstream from P_LO_L in said DNA sequence.

This feature finds its support on page 6, on lines 23 to 26 and Claims 5 and 12 of the originally filed application.

2.1.6 New Claim 15 finds its support and disclosure at page 46, lines 31 to 37 and page 47, lines 1 and 2 of the originally filed documents.

2.2 **Corrections under Rule 88 EPC**

2.2.1 In Claims 2 and 8 to the abreviations of the restriction enzymes "Sal" and "Xba" the Roman number "I" is added. The Board accepts the arguments submitted by the Appellants (see paragraph III e) above). Thus the corrections are allowable under Rule 88 EPC.

2.2.2 The amendment of page 19 of the description is allowable with regard to Rule 88 EPC since it is immediately evident that the number "73.3%" is a typing error, as in the same context throughout the description the number "73.1%" is used and thus nothing else would have been intended than what is offered as the correction.

2.3 Consequently, all amendments and corrections in the claims filed with letter of 30 March 1990 and on page 19 as filed together with the grounds for appeal are allowable with regard to Article 123(2) or Rule 88 EPC.

Order

For these reasons, it is decided that:

1. The decision of the Examining Division is set aside.

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

The Registrar

P. Martorana

The Chairman

P. Lançon

1.8.91

31.7.91

02674