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BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

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File Number: W 50/90 - 3.3.2

Application No.: PCT/GB 90/00651

Publication No.:

Title of invention: Small Polypeptides

Classification: A61K 37/02

D E C I S I O N
of 6 May 1991

Applicant: Delta Biotechnology Limited et al.

Headword: Small polypeptides/DELTA BIOTECHNOLOGY

PCT Article 17(3)(a), Rule 40.1 and 40.2(c)

Keyword: "Lack of unity "a priori" (yes) - first medical indication vs. process of preparation"

Headnote

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number : W 50/90 - 3.3.2
International Application No. PCT/GB 90/00651

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 6 May 1991

Applicant : Delta Biotechnology Limited
Castle Court
Castle Boulevard
GB - Nottingham NG7 1FD

Representative : Mr. R. Bassett
ERIC POTTER & CLARKSON
St. Mary's Court
St. Mary's Gate
GB - Nottingham NG1 1LE

Subject of the Decision : Protest according to Rule 40.2(c) of the Patent Cooperation Treaty made by the applicants against the invitation (payment of additional fee) of the European Patent Office (branch at The Hague) dated 26 July 1990.

Composition of the Board :

Chairman : P.A.M. Lançon
Members : A.J. Nuss
F. Benussi

Summary of facts and submissions

I. The Applicant filed international patent application PCT/GB90/00651.

The EPO, acting as International Search Authority (ISA) sent to the Applicant an invitation to pay one additional search fee in accordance with Article 17(3)(a) and Rule 40.1 PCT.

The ISA indicated that the subject-matter claimed related to two inventions set out as follows:

1. Claims 1-4:
   A pharmaceutical formulation comprising the 140 kDa cathepsin D fragment of fibronectin.

2. Claim 5:
   A process for the preparation of the 140 kDa cathepsin D fragment using genetic engineering techniques.

III. The Applicant paid the additional search fee under protest in accordance with Rule 40.2(c) PCT. The Applicant argued that the general inventive concept was to provide a pharmaceutical use for the 140 kDa cathepsin fragment of fibronectin.The preparation of this fragment by genetic engineering techniques, which is the subject-matter of claim 5, is only worthwhile, economically, if a pharmaceutical use, i.e. a use which should provide the Applicant with a very high return on investment, has been found, since the implementation of recombinant DNA techniques is extremely costly.

Reasons for the decision

1. The protest is admissible.

2. Rule 40.1 PCT stipulates that the invitation provided for in Article 17(3)(a) PCT must specify the reasons why the International application is deeemed not to comply with the requirements of unity of invention. The purpose of setting out reasons is to enable the Applicant and, in the case of a protest, also the Board of Appeal, to examine whether the request to pay additional fees owing to lack of unity of the invention is justified.

2.1 In an earlier published decision (W 04/85, OJ EPO 1987, 63), the Boards of Appeal expressed the view tha the requirement to give reasons in an invitation pursuant to Article 17(3)(a) PCT is so fundamental that an unsubstantiated invitation cannot be regarded as legally effective. However, this decision further states that in straightforward cases, all that may be necessary to substantiate a lack of unity is a list of the different groups of subject-matter in the application.

2.2 The invitation to the Applicant sets out as "reasons for requiring the additional fee", merely the two groups of subject-matter listed above, together with the following passage:

"Non-unity of invention was considered A PRIORI."

2.3 The present case is indeed a straightforward case and the Board therefore accepts that the invitation of the ISA is adequately substantiated, especially since the Applicant had manifestly no difficulties in understanding the objections raised by the ISA.

3. The problem underlying the invention, as it is defined in the introductory part of the description, is to provide a pharmaceutical compound which has the efficacy of fibronectin for wound healing, especially corneal wounds, but with improved availability, stability and freedom from viral contamination (see paragraph bridging page 1 and 2 of the description. According to the Applicant, the 140 kDa catepsin D fragment of fibronectin, which, he admits, is known (see page 4 lines 15-17 of the description, especially the citation of document (12) Keil-Dlouha, V. and Planchenault, T. (1986). Proc. Natl. Acad. Sci., 83; 5377-5381), solves the problem. In other words, the Applicant has found a pharmaceutical use for the 140 kDa catepsin D fragment of fibronectin (see claims 1-4).

3.1 By contrast, the 140 kDa catepsin D fragment of fibronectin being a known substance, the process for preparing said fragment (see claim 5) can only be seen as a solution to the problem of providing an alternative or, possibly, an improved process for preparing it. The Applicant indeed states in his letter of protest, that "a far simpler means of providing the peptide is known in the art" and nothing in the Application can allow the Board to conclude that this known process did not enable the man skilled in the art to prepare the fragment of interest in a satisfactory way, both quantitatively and qualitatively. And the concern to provide an alternative to this known process, even an improved one, represents manifestly a different technical problem which has nothing in common with the provision of a new use (here,pharmaceutical) for a known substance.

3.2 The two problems thereabove defined, i.e. the provision of a new use for a known substance and the provision of an alternative, possibly improved process for preparing said

substance, having a solution of their own, no technical link can be seen between them, which could form a common inventive concept and, thus, would support the unity of the invention.

3.3 Under these circumstances, the Applicant's argument according to which the claimed process would be economically a non sense if a pharmaceutical use had not be found for the fragment concerned cannot be sustained from the point of view of patent law. An economic advantage cannot be considered when assessing whether two inventions are linked so "as to form a single general inventive concept" especially when the only link between two inventions can be seen in the fact that the cost of one invention is expected to be compensated by the turnover of a second invention. What really matters, when considering unity of invention, is that from a technical point of view, the two inventions here fall under distinct inventive concepts.

4. The invitation was accordingly issued correctly and the reimbursement of the additional fee cannot be ordered.

Order

For these reasons, it is decided that:

The protest according to Rule 40.2(c) PCT is rejected.

The Registar The Chairman

P. Martorana P.A.M. Lançon