BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

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File Number: W 23/89 - 3.3.2

Application No.: PCT/US 89/01453

Publication No.:

Title of invention: Osteogenic devices

Classification: C07K 13/00

D E C I S I O N
of 23 July 1991

Applicant: Creative Biomolecules, Inc.

Headword: Osteogenic devices/CREATIVE BIOMOLECULES

EPC PCT Article 17(3)(a), Rule 13.1, 40.1 and 40.2(c)

Keyword: "Lack of unity (no) - absence of sufficiently detailed reasons in the invitation"

Headnote

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number : W 23/89 - 3.3.2
International Application No. PCT/US 89/01453

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 23 July 1991

Applicant : Creative Biomolecules, Inc.
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Representative : Mr. E.R. Pitcher
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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 14 August 1989.

Composition of the Board :

Chairman : P.A.M. Lançon
Members : U. Kinkeldey
C. Holtz

Summary of Facts and Submissions

I. The applicants filed an international patent application PCT/US 89/01453 with 33 claims.

II. The EPO acting as an International Search Authority (ISA) sent to the applicants an invitation to pay three additional search fees pursuant to Article 17(3)(a) and Rule 40.1 PCT.

III. Independent claims 1 and 2 read as follows:

"1. An osteogenic device for implantation in a mammal, said device comprising:

a biocompatible, in vivo biodegradable matrix defining pores of a dimension sufficient to permit influx, proliferation and differentiation of migratory progenitor cells from the body of said mammal; and

substantially pure osteogenic protein capable of inducing endochondral bone formation in said mammal disposed in said matrix and accessible to said cells.

2. Substantially pure osteogenic protein capable of inducing endochondral bone formation in a mammal when disposed within a matrix implanted in said mammal."

The dependent claims which follow are directed to certain embodiments of the device mentioned in claim 1 (claims 3 to 9, and 33) or to certain embodiments of the osteogenic

protein mentioned in claims 1 or 2 (claims 10 to 19 and 23 to 27). Independent claims 20 to 22 relate to methods of inducing local cartilage or bone formation (claim 20) or endochondral bone formation (claims 21 and 22).

A further independent claim, claim 28, relates to a DNA sequence encoding an amino acid sequence which induces bone or cartilage formation when implanted in a mammal in association with a matrix, whereby the DNA sequence is defined by reference to Figure 1A.

Finally, there is an independent claim 32 relating to a cell line engineered to express the protein of claim 2.

IV. Because the ISA considered the application to have failed to comply with Articles 5 and 6 PCT requirements to such an extend that a meaningful search could not be carried out (Article 17(2)(a)(ii) PCT) the search was restricted to the embodiments of claims 1 to 19, and 23 to 33, inasfar as the protein (the DNA) corresponded to the definitions given in the claims 17, 18 and 23 to 31.

With regard to non-unity the ISA found i.a. the following: "Proteins comprising some of the claimed sequences together with pertinent matrices have been already disclosed (WO 88/00205). There is therefore no common inventive concept for routinely used matrices carrying different osteogenic proteins.

The lack of a single inventive concept in the searchable part of the present application (...) makes it necessary to reconsider the technical relationship between the embodiments of the claims 17, 18 and 23 to 31."

For these reasons, the ISA regrouped the embodiments as listed below, "each subject" according to the ISA "now falling under its own inventive concept".

"1. Claims: 17 totally; 1-16, 19, 32, 33, partially:
Proteins of claim 17, and osteogenic devices containing them.

2. Claims: 18, 23, 24, 30 and 31 totally; 1-16, 19, 28, 29, 32, 33, partially:
Proteins of claims 18, 23, 24, devices for implantation containing them, and prerequisites for their recombinant production.

3. Claims: 25 and 26 totally; 1-16, 19, 28, 29, 32, 33 partially:
Proteins of claims 25 and 26, devices for implantation containing them, and prerequisites for their recombinant production.

4. Claims: 27 totally; 1-16, 19, 28, 29, 32, 33, partially:
Proteins of claim 27, devices for implantation containing them, and prerequisites for their recombinant production."

V. The applicants paid the fees under protest. In support of the protest, the applicants submitted that the basis of the non-unity holding set forth in the invitation was improper. While it was true that proteins comprising some of the claimed sequences together with pertinent matrices have been already disclosed (WO 88/00205), the cited reference failed to disclose the claimed subject-matter of the present application. The generic invention as claimed, and all of the specifically claimed sub-species, were submitted to be novel and unobvious over all of the cited

references. Accordingly there was a single inventive concept in the present application. A complete search could have been conducted readily on the subject-matter of the present application by seeking to locate disclosures of substantially pure osteogenic proteins. Each and every claim of this application required "substantially pure osteogenic protein capable of inducing endochondral bone formation in a mammal". For example, one should note that none of the references disclosed a protein having a half-maximum bone inducing activity in the range of 0.8 to 1.0 nanograms per milligram of matrix. Nor did any of the references set forth data reasonably indicating that the authors had obtained substantially pure osteogenic protein. Regarding the cited international application WO 88/00205, the authors admitted that the natural derived material was no more than "10-15% pure" or "10-50% pure". The claims of the present international application were accordingly novel over the prior art and were also not obvious.

Reasons for the Decision

1. The protest is admissible.

2. The invitation by the ISA to pay additional search fees is based on the allegation that, within the meaning of Article 17(3)(a) PCT there is a lack of a unifying inventive concept.

3. The subject-matter of independent claims 1 is directed to a device having two features. One is a matrix having certain characteristics. The other feature is described as a protein having the function of being capable of inducing endochondral bone formation in association with said matrix in a mammal. In independent claim 2 the substantially pure osteogenic protein as such is claimed.

4. From the ISA's statement that "proteins comprising some of the claimed sequences together with pertinent matrices have been already disclosed (WO 88/00205)", it may seem on the face of it, that the ISA based its objections only on lack of novelty. However, given this short statement without any reasons to support it, it is not clear to the Board whether the ISA really did object to novelty of claims 1 or 2.

5. The Board takes - after a provisional examination of its own - the position that novelty of claims 1 and 2 is not an issue in the light of document WO 88/00205. Whether or not a device according to claim 1 and a protein according to claim 2 in question lacks an inventive step in the light of document WO 88/00205 is certainly not a clear case. In the circumstances of the present case a substantial examination and an exchange of arguments with the applicants is necessary. In addition, there may be other documents than WO 88/00205 to be considered. A provisional examination, taking into account the facts of the present case as the technical field, the state of the art cited by the ISA, the ISA's position and the reasons for the protest given by the applicants, makes it anything but clear to the Board whether or not the embodiments (according to the opinion of the ISA, the proteins of claims 18, 23 and 24 (second invention), claims 25 and 26 (third invention) and proteins of claim 27 (fourth invention) still might not fall under one single inventive concept or several concepts being possibly different from those found by the ISA.

6. The sparse information given in the Invitation as cited above amounts to no more than mere allegations which may be sufficient only in clear and straightforward cases. The

present case can hardly be seen so. At least, applicants are entitled to a summary of what considerations led the ISA to draw its conclusions. This is missing here.

7. Under these circumstances the Board considers the invitation as being insufficient within the meaning of cases decided earlier (W 4/85, OJ EPO 1987, 63 and W 7/86, OJ EPO 1987, 67). In these cases, the Boards of Appeal have expressed the view that the requirement to give reasons in an invitation pursuant to Article 17(3)(a) and Rule 40.1 PCT together with the right to reasons under Article 113 EPC is so fundamental that an unsubstantiated invitation cannot be regarded as legally effective. In the present case, the invitation by the ISA provides no substantiation regarding to what extent the features of the device of claim 1 or the protein of claim 2 differ from that of document WO 88/00205 and whether or not or, for whatever reason, there no longer exists a general inventive concept with respect to claim 1 or 2.

8. The Board further would like to draw attention to a recent decision of the Enlarged Board of Appeal (G 1/89, OJ EPO 1991, 155) in which it was decided that the EPO in its function as an ISA may, pursuant to Article 17(3)(a) PCT request a further search fee where the international application is considered to lack unity of invention a **posteriori**. Insofar as it concerns the present case, the ISA correctly prosecuted when basing its invitation to pay further search fees on the allegation of lack of unity in the light of the mentioned prior art document. Taking into account, however, the problems of a substantive examination of an international application in respect of novelty and inventive step when considering under Article 17(3)(a) PCT whether the application complies with the requirements of unity of invention set forth in

Rule 13.1 PCT, the Enlarged Board of Appeal also found that the ISA may only form a provisional opinion on novelty and inventive step for the purpose of carrying out an effective search (point 8.1 of the decision). Furthermore (see point 8.2 of the decision), the Enlarged Board of Appeal added that the consideration by an ISA of the requirement of unity of invention should, of course, always be made with a view to giving the applicant fair treatment and that the charging of additional fees under Article 17(3)(a) PCT should be made only in clear cases. In particular, in view of the fact that such considerations under the PCT are being made without the applicant having had an opportunity to comment, the ISA should exercise restraint in the assessment of novelty and inventive step and in borderline cases preferably refrain from considering an application as not complying with the requirement of unity of invention on the ground of lack of novelty or inventive step.

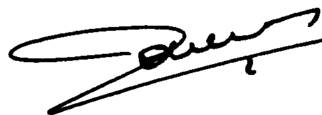
9. The invitation having no legal effect, and a provisional examination not clearly leading to the conclusion of non-unity, the conditions of Rules 13.1 and 13.2 PCT are fulfilled. The additional fees, therefore, have to be reimbursed.

Order

For these reasons, it is decided that:

Refund of the additional search fees is ordered.

The Registrar: The Chairman:



P. Martorana P. Lançon

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