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File Number: W 26/91 - 3.3.2

Application No.: PCT/US90/06849

Publication No.: WO 9108298

Title of invention: Hybrid immunoglobulins

Classification: C12N 15/62

D E C I S I O N
of 8 September 1992

Applicant: Genentech, Inc.

Headword: Hybrid immunoglobulins/GENENTECH

PCT Article 17(3)(a) and Rules 13 and 40

Keyword: "Lack of unity a priori - (no)"
"Lack of unity a posteriori - invitation not sufficiently reasoned"

Case Number : W 26/91 - 3.3.2
International Application No. PCT/US 90/06849

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 8 September 1992

Applicant : Genentech, Inc.
460 Point San Bruno Boulevard
South San Francisco, California 94080 (US)

Representative :

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 16 April 1991.

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/US90/06849 with 49 claims.

II. The EPO acting as an International Search Authority (ISA) sent to the Applicants an invitation to pay six additional search fees pursuant to Article 17(3)(a) and Rule 40.1 PCT. It considered that the application did not comply, a priori and a posteriori, with the requirement of unity of invention as set forth in Rule 13.1 PCT. With regard to lack of unity a priori the ISA stated that "the subjects, defined by the problems and their means of solution as listed below are so different from each other that no technical relationship can be appreciated to be present so as to form a single inventive concept:

Claims 1-37, 39-40, 42-49 relate to fusion proteins comprising one ligand binding partner and a stable plasma protein

Claims 38 and 41 relate to fusion proteins comprising two different ligand binding partners and two preferably different stable plasma proteins. Accordingly no search was performed for Claims 38 and 41."

As far as lack of unity a posteriori was concerned the ISA stated: "The general problem underlying the invention is not novel and a solution to it has already been found or does not involve an inventive step having regard to the state of the art as illustrated by

a) EP-A-2 325 224
b) Nature, Vol. 339, pages 68-70
c) EP-A-2 325 262
d) EP-A-2 314 317

Therefore, the original single general inventive concept is not acceptable any more, making it necessary to reconsider the technical relationship between the different solutions mentioned. This leads to the regrouping under distinct subjects as listed below, each subject now falling under its own inventive concept."

There follows a list of six groups of inventions by mentioning the respective claims considered to belong to these groups.

III. The Applicants paid six additional search fees under protest and submitted that the international patent application complied with the requirement of unity of invention as defined in Rule 13 PCT, and in any event, the amount of the required additional search fee was highly excessive.

As far as the objection to lack of unity a priori was concerned the Applicants argued that the subject-matter of Claims 1 to 37, 39 to 40 and 42 to 49, defined as a first group by the ISA on the one hand and the subject-matter of Claims 38 and 41 defined as a second group of invention, did belong to one single inventive concept, because the claims of the first group covered polypeptide fusions comprising a ligand binding partner protein and a stable plasma protein, nucleic acids encoding such polypeptide fusions, expression vectors comprising the encoding nucleic acids, cells transformed with such expression vectors, and methods of culturing such cells, whereas on the other hand the claims of the second group covered polypeptide fusions which comprised the fusion of the first ligand binding partner protein and a stable plasma protein (similar to the claims within the first group), along with an additional fusion as defined in the respective claims.

Accordingly, the claims of the second group of invention defined a specific embodiment of the polypeptides defined in the claims of the first group and related to the same inventive concept, namely the provision of novel hybrid immunoglobulin molecules comprising the fusion of ligand binding partners to stable plasma proteins. All such fusions combined the adhesive and targeting characteristics of a ligand binding partner with immunoglobulin effector functions, although they may possess additional properties.

Technically, Claims 38 and 41, identified as second group of invention, could have been made dependent on Claim 1 to emphasise that they narrow the scope of that claim. However, this was not a requirement, as Rule 13.3 PCT specifically permits to include two or more independent claims of the same category in the same international application.

As to the objection to lack of unity a posteriori the Applicants submitted essentially the following arguments:

The practice of the International Search Authority (ISA) to carry out an a posteriori examination of an international application and to find non-unity based on the discovery of document(s) allegedly anticipating one or more of the generic claims was at the borderline of the ISA's authority and therefore the ISA's burden to prove any such conclusion was strict. In the present case the Applicants were provided with a mere listing of four references from the search report, with a "lack of novelty" statement, and with the regrouping of claims. If the ISA arrogated the right to conduct a preliminary examination of an international application in the searching phase, it should also hold itself to the standards of the preliminary examination authority in

providing sufficient reasons of why the citations would anticipate or make obvious one or more of the generic claims. This had not been done in the case of the present application and therefore the a posteriori finding of non-unity was improper.

There were furthermore obvious errors in the invitation by the ISA, which might be one reason for the erroneous finding of a posteriori lack of unity. These were: (i) not considering the definitions of terms "ligand binding partner" and "stable plasma protein" as provided on pages 7 to 9 of the specification; (ii) the artificial differentiation between the claims related to a fusion of an immunoglobulin to a cell membrane protein and the claims drawn to fusion of immunoglobulins with LHR, given that LHR was a membrane-bound protein; and (iii) the reference to Claim 24 in the fourth group enumerated in the invitation by the ISA which clearly did not relate to a fusion of an immumoglobulin and cell membrane protein. What could have been referred to in the latter case is Claim 23, which in turn was incorrectly grouped with claims covering fusions of immunoglobulins with constant region-like domains of immunoglobulin super family members.

Reasons for the Decision

1. The protest is admissible.

2. Lack of unity a priori

2.1 The ISA found lack of unity a priori, i.e. without considering prior art found during the search, of Claims 38 and 41 in comparison with the rest of the claims. As correctly submitted by the Applicants,

Claims 38 and 41 relate - as does Claim 1 - to a polypeptide fusion comprising a first ligand binding partner and a stable plasma protein, said fusion according to Claims 38 and 41 further comprising an additional fusion of a second ligand binding partner and a second stable plasma protein. To the subject-matter common to all these claims is added a second feature in Claims 38 and 41 which does not change the technical character of Claims 38 and 41 such that on the face of it an a priori lack of unity could be be recognised. Rather, it is one of the standard methods of drafting claims relating to certain embodiments of a main claim to incorporate further features, which may well be a further product as in the present case.

2.2 Consequently the invitation to pay an additional search fee because of lack of unity a priori was not justified.

3. Lack of unity a posteriori

3.1 Rule 40.1 PCT requires that the invitation to pay additional search fees has to be reasoned. By this requirement it is ensured that the justification of the requested additional fees can be reviewed by the Board of Appeal.

3.2 What was stated by the ISA in its invitation as "reasons" amounts to no more than the conclusion that the general problem underlying the invention was not novel and a solution to it had already been found or did not involve an inventive step having regard to the state of the art as illustrated by the mere listing of four prior art documents. Three of these documents are European patent applications counting 40 to 60 pages and describing inter alia pages of DNA- and amino acid-sequences. None of the considerations leading up to this conclusion is given, for

example what exactly in these documents is novelty destroying or making the solution obvious. Nor is it stated which prior art document was considered to be the closest prior art, or the problem identified in the light of this prior art.

Finally, there is not the slightest hint as to what was considered to be no longer novel and what was considered to be no longer to be inventive of the subject-matter of the international patent application.

3.3 From the above follows that the Board is not in a position to review the justification of the invitation to pay the additional search fees a posteriori and, therefore, the invitation is not legally effective because of of its non-compliance with the requirements of Rule 40.1 PCT.

3.4 The invitation by the ISA might further be considered as to contravene the principles laid down by the Enlarged Board of Appeal in Decision G 1/89 (OJ EPO 1991, 145), namely that the Applicants should be given a fair treatment when considering the requirement of unity of invention and that additional fees should be charged under Article 17(3)(a) PCT only in clear cases. The mere citation of three extensive documents without any analysis of what was disclosed in these documents and the undifferentiated allegation that with regard to these documents there is no novelty or inventive step cannot be considered as a fair treatment.

4. Consequently there was no justification for charging additional search fees, either a priori or a posteriori.

Order

For these reasons, it is decided that:

Reimbursement of the additional fees paid by the Applicants is ordered.

The Registrar:

P. Martorana

The Chairman:

P. Lançon

23.9.92

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