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: W 5/91 - 3.3.2

Application No.: PCT/GB90/01079

Publication No.:

Title of invention: Pharmaceutical compositions

Classification: A61K 31/495

D E C I S I O N
of 10 September 1991

Applicant: National Research Development Corporate et al

Headword: Bis-dioxopiperazines/NRDC

PCT Article 17(3)(a), Rules 40.1, 40.2(c)

Keyword: "Unity of invention
(no - subsequent different medical indications)"
(yes - second medical indication for compounds of a general formula and first medical indication (product claim) for compounds of a more restricted formula)"

Headnote

There is a prima facie unity of invention between a claim to the use of chemical compounds defined by a general formula (second medical indication) and a product claim relation to a more restricted group of compounds falling within the said general formula (first medical indication).

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number : W 5/91 - 3.3.2
International Application No. PCT/GB90/01079

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 10 September 1991

Applicant : National Research Development Corporation
101 Newington Causeway
London SE1 6BU (GB)

Representative : Mr. G.F. Stephenson
Patent Department
National Research Development Corporation
101 Newington Causeway
London SE1 6BU (GB)

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 22 November 1990.

Composition of the Board :

Chairman : P.A.M. Lançon
Members : I.A. Holliday
E.M.C. Holtz

Summary of Facts and Submissions

I. The Applicant filed international patent application PCT/GB90/01079.

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

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

1. Claims 1-15 : Use of a compound of formula II as a cardioprotective agent.

2. Claims 23; 25 in part : Use of a compound of formula II for providing protection against the toxic effects of paracetemol.

3. Claims 24; 25 in part : Use of a compound of formula II for providing protection against damage caused by free radicals.

4. Claims 16-22, 26, 27 : Novel compounds, pharmaceutical compositions thereof.

Having regard to Rule 39.1(iv) PCT, the ISA had not carried out a search in respect of Claim 28.

III. The Applicant paid the additional search fees under protest in accordance with Rule 40.2(c) PCT. The Applicant

argued that the separate medical indications which formed the subject-matter of Claims 1, 23 and 24 belonged to the same general inventive concept and referred to the "Guidelines for Examination in the EPO", part C, Chapter IV, paragraph 4.2 in support of the argument. It was further argued that Rule 13.2 PCT permitted the inclusion in the same international application of an independent claims to the use of a product together with a claim to the product per se. It was accordingly the Applicant's view that the product claims, designated above as the fourth invention, also belonged to the same general inventive concept.

The Applicant also mentioned a corresponding European application No. 90 307 685.9 (publication No. 0 409 499) which, on the basis of analogous claims, the Search Division of the EPO had considered to relate only to three inventions.

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 deemed not to comply with the requirements of unity of invention. The purpose of setting out reasons it 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 that 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 the reasons for requiring the additional fee, merely the list of the four groups of subject-matter listed above together with a note to the effect that Claim 28 had not been searched.

2.3 In the opinion of the Board, the present case can be considered straightforward since it was immediately clear that the ISA considered the three medical indications to be unrelated and furthermore that the fourth invention listed was not homogeneous with that of the compounds referred to in use Claims 1, 23 and 24. It is also apparent that the Applicant had no difficulties in understanding the objections raised by the ISA. Since the reasons make no reference to the state of the art revealed by the international search, it is apparent that an objection a priori is intended.

3. In the case of a protest under Rule 40.2 PCT, where an objection a priori is raised, no examination of the merits of the claim in comparison with the state of the art has been carried out. The only way to determine the technical problem (in contradistinction to the normal approach) is to rely on the description of the application and the provisional acknowledgement of the prior art therein, if given.

3.1 According to the description, certain bis-dioxopiperazines are known together with medical indications including cardioprotection against the toxic effects of daunorubicin

as well as use in the treatment of cancer and lead poisoning. Thus, the problem underlying the present application can be seen in providing further medical uses for the bis-dioxopiperazines specified on page 3 of the description and which are referred to in Claims 1, 23 and 24.

3.2 The problem is solved by the three medical indications which form the subject-matter of the above-mentioned claims. The Applicant has argued that the said indications are related and especially that the cardioprotective effect may also involve protection against the damage caused by fee radicals. There is, however, no unambiguous evidence on this point; the description on page 16 (lines 17-19) merely states that the effects may be related. Thus, the Board share the opinion of the ISA that there is a lack of coherence between the three medical indications of Claims 1, 23 and 24 and that the requirements of Rule 13.1 PCT are not satisfied.

3.2.1 The above finding is not in conflict with Guidelines, Part C, IV, 4.2 referred to the Applicant, where it is stated that where an applicant discloses "subsequent" therapeutic uses, the said uses are allowable in a single application only if they form a single general inventive concept.

3.3 As far as Claims 16-22, 26 and 27 are concerned, the said claims relate in general to a pharmaceutical composition comprising a bis-dioxopiperazine of the general Formula II which also features in Claims 1, 23 and 24. The definition of Claim 16, however, contains further disclaimers over that on Claims 1, 23 and 24. In other words, it is restricted to a narrower groups of compounds of Formula II, which the Applicant believed to be new (and inventive) at the priority date of the application. It is

current practice before the EPO to allow, in the same application, a claim to the use of chemical compounds defined by a general formula, together with a product claim relating to a more restricted group of chemical compounds which fall within the said general formula (cf. decision W 13/89 of 12 July 1990, not published in OJ EPO). There is accordingly no reason a priori why the pharmaceutical compositions of Claim 16 (narrower definition of compound II - first medical indication) should not be included in the same application as the use defined by Claim 1 (broader definition of compound II - second medical indication). Moreover, such a grouping of inventions is in accordance with Rule 13.1(i) PCT. Accordingly, one of the additional search fees should be returned to the Applicant.

Order

For these reasons, it is decided that:

Reimbursement of one of the additional fees to the Applicant is ordered.

The Registrar: The Chairman:

P. Martorana P. Lançon