BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

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File Number: W 52/92 - 3.3.2

Application No.: PCT/GB92/01083

Publication No.: WO 93/00094

Title of invention: Medicaments

Classification: A61K 31/55

D E C I S I O N
of 2 April 1993

Applicant: Smithkline Beecham Plc

Headword: Medicaments/SMITHKLINE

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

Keyword: "Lack of unity a priori (no)"

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number : W 52/92 - 3.3.2
International Application No. PCT/GB92/01083

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 2 April 1993

Applicant : Smithkline Beecham Plc
New Horizons Court, Brentford
Middlesex TW8 9EP (GB)

Representative : Smithkline Beecham
Corporate Patents
Att. Mrs J.A. Florence
Mundells
Welwyn Garden City
Herts AL7 1EY (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 30 September 1992.**

Composition of the Board :

Chairman : P.A.M. Lançon
Members : A.J. Nuss
S.C. Perryman

Summary of Facts and Submissions

I. The Applicants filed International Patent Application PCT/GB 92/01083 on 17 June 1992. The application contained 12 claims.

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

According to the ISA, the two medical indications mentioned in the claims, viz. portal hypertension and migraine, were not related and belonged thus to different fields of medical science. Since there was no relationship nor link between these medical indications the only common and linking inventive concept would be the use of the present compounds in therapy, a problem which had already been solved in the state of the art. Moreover, since each medical field would have its own particular state of the art and because of the heterogenity of the medical fields, separate search strategies would be necessary; thus, one common search could not be performed in a complete and exhaustive way. Because of this lack of unity a priori, the application had to be divided into the following two subjects, the first of which had been searched:

1. Claims 1-5 (partially), 6-11: Use of the compounds of the invention for the treatment of portal hypertension. New compounds, pharmaceutical compositions containing them and a process for their preparation.

2. Claims 1-5 (partially), 12: Use of compounds of the invention for the treatment and prophylaxis of migraine.

III. The Applicants paid the additional fee under protest.

In support of their protest, they argued in essence that a search had been conducted by the ISA for compounds per se. This should have located any pertinent references to the compounds, whatever their utility. They considered any additional search directed to the use of the compounds in migraine to be unnecessary because in their opinion such a search would not locate any documents of more relevance than those already cited in respect of the compounds.

Reasons for the Decision

1. The protest is admissible.

2. In the present case the ISA denied lack of unity on an a priori basis. As repeatedly pointed out by the Boards of Appeal, the only way to determine the technical problem in such a case (in contradiction to the normal "problem and solution approach") is to rely on the description of the application and the provisional acknowledgment of the prior art therein, if given.

2.1 According to the description, certain tetrahydro-benzazepines are known in the art for the treatment of gastrointestinal mobility disorders. Thus, the problem underlying the present application can be seen in providing a further medical use for the tetrahydro-benzazepine derivatives referred to in the claims and description of the international application as compounds of structure (I). At least as far as the EPO is concerned such further medical use is patentable (cf. decision of the Enlarged Board of Appeal, G 5/83, OJ EPO, 1985, 64).

2.2 This problem is solved by providing as a further medical use for the said compounds the treatment of disorders characterised by excessive vasodilation, in particular the treatment or prophylaxis of portal hypertension and migraine.

2.3 As stated in the description, this medical utility is ascribed to the fact that the compounds of structure (I) are agonists at 5-HT_2 and/or 5-HT_1-like receptors which are believed to be effective in a) portal hypertension through constriction of mesenteric arterioles, and partial constriction of paraesophageal collaterals with consequent reduction of portal flow and portal pressure and b) migraine through constriction of cerebral arteries (5-HT_1-like agonists) and constriction of temporal artery (5-HT_2 agonists). It is thus clear that contrary to the assertion of the ISA portal hypertension and migraine are two deseases which are closely related in that both result from disorders due to excessive vasodilation, which the present application proposes to treat with specific vessel constricting medicaments, i.e. agonists at 5-HT_2 and/or 5-HT_1-like receptors, among which figure the tetrahydrobenzazepine derivatives of structure (I) mentioned above (see page 1, lines 4 to 11 and lines 21 to 25; page 6, line 19 to page 7, line 32).

2.4 Although there is no mention in the invitation that Claims 9 to 12 are broader in scope than the main claim in that they relate to the use of a "5-HT_1-like receptor and/or 5-HT_2 receptor agonist" in the treatment of portal hypertension and to the use of a "5-HT_2 receptor agonist" in the treatment and prophylaxis of migraine, the Board would like to observe that there is no reason a priori why these claims should not be included in the present application, provided they are correctly reformulated in due time as "first medical indication" - claims (e.g. 5-HT_2

receptor agonist for use in the treatment of portal hypertension). As can be seen from point 2.3 above, use of functional terminology defining the result to be achieved instead of a definition by structure must, at least at this stage of the proceedings, be considered to be justified by the total information content of the disclosure as a whole.

3. It follows from the preceding considerations that the requirement of unity of invention in the sense of Rule 13.1 PCT is satisfied in the present case. Accordingly, the additional search fee should be reimbursed.

Order

For these reasons, it is decided that:

Refund of the additional search fee is ordered.

The Registrar: The Chairman:

P. Martorana P. A. M. Lançon