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D E C I S I O N
of 16 March 2000

Case Number: T 0563/97 - 3.3.1

Application Number: 94917637.4

Publication Number: 0699194

IPC: C07D 401/06

Language of the proceedings: EN

Title of invention:
5-HT4 Receptor Antagonists

Applicant:
SMITHKLINE BEECHAM PLC

Opponent:
-

Headword:
Antagonist/BEECHAM

Relevant legal provisions:
EPC Art. 82, 113(1), 123(2)
EPC R. 67

Keyword:
"Unity of invention a posteriori (yes - after amendment) - second medical use - special technical feature"
"Reimbursement of appeal fee (no) - not equitable - fresh document not causal for the necessity to file the appeal"

Decisions cited:
G 0001/83, T 0830/90, J 0032/95

Catchword:

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Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0563/97 - 3.3.1

D E C I S I O N
of the Technical Board of Appeal 3.3.1
of 16 March 2000

Appellant: SMITHKLINE BEECHAM PLC
New Horizons Court
Brentford
Middlesex TW8 9EP (GB)

Representative: Tocher, Pauline
SmithKline Beecham plc
Corporate Intellectual Property
Two New Horizons Court
Brentford
Middlesex TW8 9EP (GB)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 9 April 1997 refusing European patent application No. 94 917 637.4 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: A. J. Nuss
Members: R. Freimuth
R. T. Menapace

Summary of Facts and Submissions

I. The appeal lodged on 21 April 1997 lies from the decision of the Examining Division posted on 9 April 1997 refusing European patent application No. 94 917 637.4 (European publication No. 699 194), which was filed as international application published as WO-A-94/27987.

II. The decision of the Examining Division was based on claims 1 to 12 filed with the letter dated 12 August 1996 according to the then pending request. The Examining Division refused the application on the sole ground that the claimed subject-matter lacked unity, thus contravening Article 82 EPC, in particular because the common structural feature of the claimed compounds, i.e. the linker unit -CO-CH_2-, was already known, even in pharmaceutically active compounds, from the documents

(1) EP-A-0 173 585 and

(2) DE-A-2 618 152.

III. The Appellant (Applicant) submitted amended claims 1 to 12 together with the Statement of Grounds of Appeal filed on 21 April 1997. The independent claims 1, 6, 9 and 10 read as follows, claim 1 being reproduced below only to the extent necessary for understanding this decision:

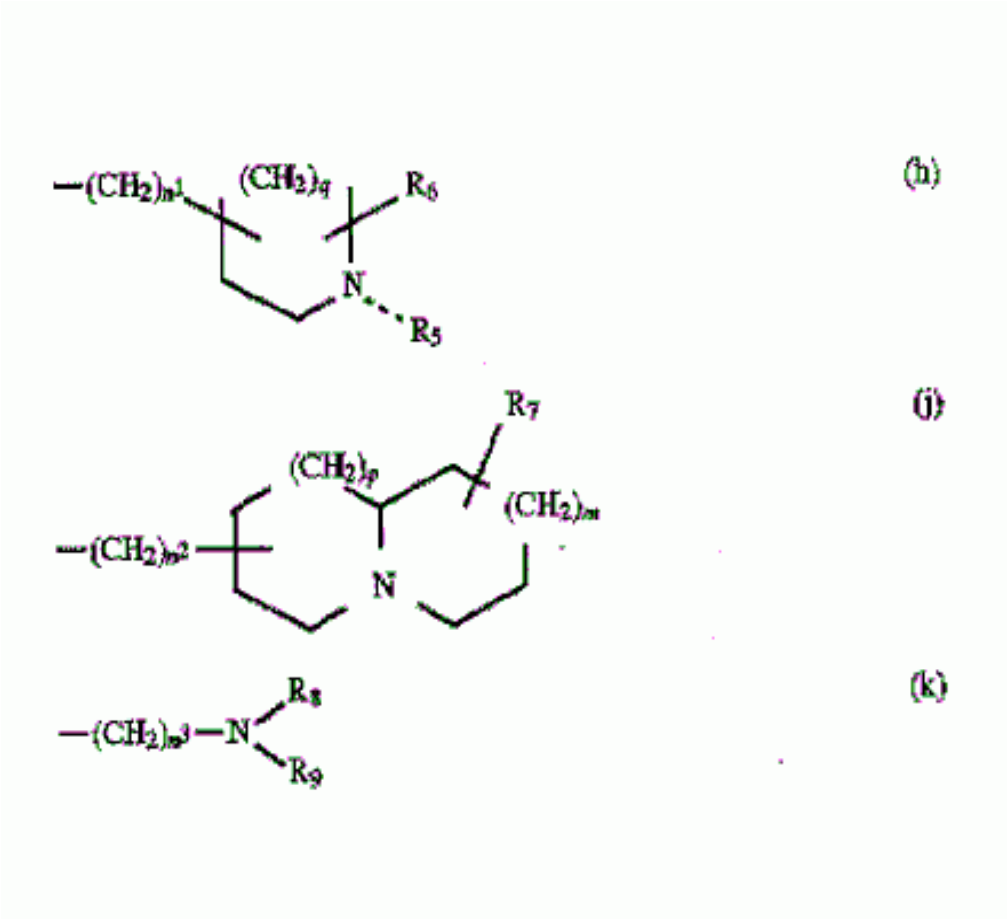
"1. Use of a compound of formula (I) or a pharmaceutically acceptable salt thereof:

$$X\text{-}CO\text{-}CH_2\text{-}Z \qquad (I)$$

wherein

X is a monocyclic or polycyclic aromatic group, such as a group of formula (a), (b), (c), (d), (e), (f) or (g): [...];

Z is of subformula (h), (j) or (k):



wherein

n^1 is 1, 2, 3 or 4; n^2 is 0, 1, 2, 3 or 4; n^3 is 2, 3, 4 or 5;

q is 0, 1, 2 or 3, p is 0, 1 or 2; m is 0, 1 or 2;

R_5 is hydrogen, $C_{1\text{-}12}$ alkyl, aralkyl, or R_5 is $(CH_2)_z\text{-}R_{10}$ wherein z is 2 or 3 and

R_{10} is selected from cyano, hydroxyl, $C_{1\text{-}6}$ alkoxy, phenoxy, $C(O)C_{1\text{-}6}$ alkyl, COC_6H_5, $-CONR_{11}R_{12}$, $NR_{11}COR_{12}$, $SO_2NR_{11}R_{12}$, $NR_{11}SO_2R_{12}$ wherein R_{11} and R_{12} are hydrogen

or C_{1-6} alkyl; or R_5 is straight or branched chain alkylene of chain length 1-6 carbon atoms terminally substituted by 3 to 8 membered cycloalkyl, 3 to 8 membered heterocyclyl, 5 or 6 membered monocyclic heteroaryl or 9 to 10 membered fused bicyclic heteroaryl linked trough carbon, C_{2-7} alkoxycarbonyl, or secondary or tertiary hydroxy substituted C_{1-6} alkyl; and

R_6, R_7 and R_8 are independent hydrogen or C_{1-6} alkyl; and

R_9 is hydrogen or C_{1-10} alkyl;

in the manufacture of a medicament for use as 5-HT_4 receptor antagonist.

6. A compound of formula (I) as defined in claim 4 or 5.

9. A pharmaceutical composition comprising a compound according to any one of claims 6 to 8, and a pharmaceutically acceptable carrier.

10. A compound according to any one of claims 6 to 8 for use as an active therapeutic substance."

IV. The Appellant argued that the amendments as now made to the claims overcame the objections raised in the decision under appeal. The documents (1) and (2) did not teach or suggest that the compounds used in the present application would have 5-HT_4 receptor antagonist properties. Even if related compounds had been described in that state of the art, those compounds fell within a different art field with the consequence that they would not constitute a reason for the claimed invention to lack unity.

Furthermore, the Appellant argued that solely the objection of non-unity was properly raised in the only communication of the Examining Division dated 19 April 1996 which the Appellant addressed in his response. Other objections were not specifically identified in that communication and their extent was not clear. Moreover, the communication of the Examining Division referred to the International Preliminary Examination Report established under the Patent Cooperation Treaty (PCT) which cited the sole document (2). Nevertheless, the decision under appeal addressed two documents, i.e. (1) and (2). Additionally, according to the Appellant, he drew the Examining Division's attention to a particular document which could be relevant for assessing novelty, but no comment was made thereon in the decision under appeal. Therefore it was "inappropriate" for the Examining Division to refuse the application at the present stage of prosecution.

The Appellant requested (implicitly) that the decision under appeal be set aside and (explicitly) that the appeal fee be refunded.

Reasons for the Decision

1. The appeal is admissible.

2. The substantive issues arising from this appeal are whether or not the claimed invention satisfies the requirements of Article 82 EPC, which is stated in the decision under appeal as being the sole ground for refusal of the application, and whether or not the amendments made to the claims meet those of

Article 123(2) EPC.

3. *Amendments (123(2) EPC)*

Claims 1 to 5 are based on claim 10 as filed in combination with claims 1 to 5 of the application as filed, including an obvious correction of the index of the substituent R in claim 3 in order to comply with the general formula (h). Claims 4 to 11 as filed and example 2 d) of the application as filed support claims 6 to 11. Claim 12 is backed up by page 8, lines 9, 13, 20 and 21 of the application as filed.

For these reasons, the Board concludes that the claims 1 to 11 as amended meet the requirements of Article 123(2) EPC.

4. *Unity (Article 82 EPC)*

4.1 Lack of unity may be directly evident *a priori*, i.e. before the examination of the merits of the claims in comparison with the state of the art, or alternatively *a posteriori*, i.e. after having taken into consideration the prior art. In the present case, the non-unity objection was based on the subject-matter disclosed in documents (1) and (2) (see point II above) and was thus made *a posteriori*.

4.2 When deciding on unity of invention, it is mandatory under Article 82 EPC to determine whether or not a group of inventions claimed in the application forms a single general inventive concept. The Implementing Regulations to the EPC, in particular Rule 30(1), specify the method for determining whether the

requirement of unity of invention is fulfilled. That rule calls for the presence of a technical relationship among those inventions involving one or more of the same or corresponding special technical features in order to establish unity of invention. The expression "special technical features" shall mean those features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

4.3 Claim 1 is directed to the use of compounds of general formula (I) or pharmaceutical acceptable salts thereof in the manufacture of a medicament for use as a 5-HT_4 receptor antagonist. Some compounds *per se* form part of the state of the art since pharmaceutically active compounds satisfying that general formula (I) are already disclosed in documents (1) and (2), the compounds of document (1) having antiarrhythmic properties and those of document (2) showing psychotropic, in particular antidepressive, effects. In the light of that prior art, the problem to be solved by the present application consists in providing a further medical use for compounds of general formula (I), such as those disclosed in documents (1) and (2).

4.4 Claim 1 has been reformulated in appeal proceedings in accordance with the principles laid down in the decision G 1/83 (OJ EPO 1985, 64) to refer to the use of the compounds of general formula (I) for the manufacture of a medicament for a particular (second) medical indication. Thus, the particular (second) medical indication, i.e. the 5-HT_4 receptor antagonist activity, is the feature characterizing the present invention. There is nothing on file showing any

relationship between the effects mentioned in documents (1) and (2), and the 5-HT_4 receptor antagonist activity of the present invention. The latter feature, which is therefore new and non-obvious in view of documents (1) and (2), hence, defines the contribution which the present invention, considered as a whole, makes over that prior art with the consequence that it constitutes a "special technical feature", as required by Rule 30(1) EPC.

For these reasons, documents (1) and (2) relied upon in the decision under appeal can no longer serve as a basis for an objection of non-unity *a posteriori* pursuant to Article 82 EPC against claim 1, having regard to Rule 30(1) EPC.

4.5 The new compounds claimed *per se* and in the form of a first medical indication in independent claims 6 and 10, respectively, are all covered by the general formula (I) of claim 1 and contribute to the solution of the problem as set out in point 4.3 above. Thus, they form part of the same general inventive concept in terms of Article 82 EPC. The same conclusion applies necessarily to the pharmaceutical compositions of independent claim 9 comprising a compound according to claim 6 and, by the same token, to claims 2 to 5, 7, 8, 11 and 12 depending on claims 1, 6 and 10, respectively.

4.6 Therefore, the Board concludes that the present invention as defined in the claims meets the requirement of unity of invention within the meaning of Article 82 EPC.

5. *Remittal*

In these circumstances, the substantive examination not having been concluded, the Board considers it appropriate to exercise the power conferred on it by Article 111(1) EPC to remit the case to the Examining Division for further prosecution.

6. *Reimbursement of appeal fees (Rule 67 EPC)*

6.1 The Appellant argued that objections other than lack of unity pursuant to Article 82 EPC were not specifically identified in the only communication of the Examining Division dated 19 April 1996. The decision under appeal being based on the sole ground of lack of unity, which had adequately been raised as conceded by the Appellant, the limitation to that ground in the decision cannot constitute a procedural violation. Neither was the decision premature, because the Appellant, in the view of the Examining Division, had failed to remove the objection under Article 82 EPC in his response to the Examining Division's communication (see decisions cited in Case Law of the Board of Appeals of the EPO, 1999 edition, VII.B.3.1)

6.2 The further objection of the Appellant that the Examining Division did not comment on a particular intermediate document cited by the Appellant in respect of novelty pursuant to Article 54(3) EPC shares the same fate since lack of novelty is not a ground on which the decision under appeal is based and, thus, is irrelevant in the present case.

6.3 As regards the Appellant's criticism that the appealed

decision relied also on document (1) which had been cited neither in the communication of the Examining Division nor in the International Preliminary Examination Report incorporated in that communication by way of explicit reference, it is pointed out that the reimbursement of the appeal fee is not equitable under Rule 67 EPC where the substantial procedural violation is not relevant to the outcome of the proceedings (see decision J 32/95, OJ EPO 1999, 713, point 3.5 of the reasons and the jurisprudence cited therein, in particular the decision T 893/90, point 5.2 of the reasons, not published in OJ EPO).

In the decision under appeal documents (1) and (2) were cited as evidence for one and the same fact, namely that a specific feature of claim 1 was known. The reasons given for the decision under appeal would have been substantiated and valid, and had led to the same finding, even if only document (2) - the one explicitly mentioned in the International Preliminary Examination Report and incorporated in the communication of the Examining Division by way of reference - had been cited in the decision under appeal. Thus, in the present case there is no causal link between the citing of document (1) in addition to document (2) in the decision under appeal, and the necessity to file an appeal, in the sense that the Appellant would not have had to file an appeal and to pay the prescribed fee had the Examining Division not mentioned also document (1) in the reasons for the impugned decision. As a result, the reimbursement of the appeal fee cannot be considered equitable in the circumstances of the present case independently of the question of whether or not the citing of document (1) amounted to a substantial

procedural violation.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance for further prosecution.

3. The request for reimbursement of the appeal fee is rejected.

The Registrar: The Chairman:

E. Görgmaier A. Nuss