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Bezeichnung der Erfindung: Method for the treatment of dyslipidemia in humans
Title of invention:
Titre de l'invention :

Klassifikation / Classification / Classement : A61K 31/60

ENTSCHEIDUNG / DECISION
vom / of / du 12 July 1990

Anmelder / Applicant / Demandeur : Schering Corporation

Patentinhaber / Proprietor of the patent /
Titulaire du brevet :

Einsprechender / Opponent / Opposant :

Stichwort / Headword / Référence :

EPÜ / EPC / CBE PCT Article 17(3)(a); Rule 13.1 and 13.2 and Rule 40.2(c)

Schlagwort / Keyword / Mot clé : "Unity of invention (yes)"

Leitsatz / Headnote / Sommaire

There is a prima facie unity of invention between a claim to the use of a mixture or its separate components for the manufacture of a medicament for a specific indication (second medical indication) and a claim to the mixture only as a pharmaceutical composition (first medical indication).

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Case Number : W 13/89
International Application No. PCT/US 88/04199

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 12 July 1990

Appellant : Schering Corporation
2000 Galloping Hill Road
Kenilworth, New Jersey 07033
US

Representative : Blasdale, John H.C.
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Subject of this 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 19 May 1989**

Composition of the Board :

Chairman : P. Lançon
Members : I. Holliday
C. Holtz

Summary of Facts and Submissions

I. The Applicant filed International Patent Application PCT US 88/04199.

II. The EPO acting as International Search Authority (ISA) sent to the Applicant an invitation to pay an additional search fee in accordance with Article 17(3)(a) and Rule 40.1 PCT. The said invitation indicated that the ISA considered that the above mentioned application related to the following groups of subject-matter which did not satisfy the criteria of unity of invention:

1. Claims 6-8: Pharmaceutical composition containing the (S,R) isomer of labetalol and optionally the (R,R) isomer as further active ingredient

2. Claims 9-10: Use of (S,R) and/or (R,R) labetalol for the manufacture of a medicament for treating dyslipidemia.

The ISA argued that it was apparent from the prior art cited that Claim 6 lacked novelty. An objection to the lack of a common inventive concept between the subjects listed above was then raised.

Claims 1-5 which related to non-patentable subject-matter were not searched in accordance with Rule 39.1(iv) PCT.

III. The Applicant paid the additional search fee but under protest. In support of the protest, the Applicant maintained that the ISA had not mentioned Claim 7 which related to a pharmaceutical composition containing a

mixture of the (S,R) and (R,R) isomers of labetalol which was substantially free of the corresponding (S,S) and (R,S) isomers. The Applicant argued that Claim 7 was parallel to one of the embodiments of Claim 9 which related to the use of either the (S,R) or (R,R) isomer or both or a pharmaceutically acceptable salt for the manufacture of a medicament for treating dyslipidemia in humans.

Reasons for the Decision

1. The protest is admissible.

2. According to Rule 13.1 PCT, the international patent application shall relate to one invention only or to a group of inventions so linked as to form a single inventive concept.

3. The present case relates to a protest against a non-unity objection raised in consequence of a novelty objection. It is accordingly possible to identify the technical problem to be solved by referring to the prior art.

The compound 5-{[1-hydroxy-2-[(1-methyl-3-phenylpropyl)amino]ethyl}salicylamide otherwise known as labetalol exists as four stereo isomers, i.e. 5{[(R)-1-hydroxy-2-[(R)-(1-methyl-3-phenylpropyl)amino]ethyl} salicylamide together with corresponding (R,S), (S,R) and (S,S) isomers. From the prior art referred to in the application, e.g. J. Med. Chem., Vol. 25, pages 1363-70 (1982), it was acknowledged that the (R,R)-isomer had an antihypertensive effect. Accordingly, pharmaceutical compositions per se based on the (R,R)-isomer were not claimed, Claim 6 of the application relating only to compositions comprising the (S,R)-isomer which are substantially free of the (S,S)- and (R,S)-isomers. The

Board observes that no objection a priori has been raised by the ISA against Claims 6 and 9 although no parallism existed.

It is now apparent from the new prior art cited by the ISA, e.g. Br. J. Pharmac., Vol. 77, 1982, pages 105-114, that not only the (R,R)-isomer but also the (S,R)-isomer have known medical uses, each having adrenergic blocking properties. The (R,R)-isomer has β_1-blocking activity and the (S,R)-isomer α-blocking activity. Accordingly, Claim 6 of the application indeed lacks novelty.

Thus, it appears that the a posteriori objection of lack of unity raised by the ISA is based on the grounds that, on the one hand, Claim 7 relates to a pharmaceutical composition based on a mixture of the (S,R)- and (R,R)-isomers. Claim 9, on the other hand, relates to the use of a compound "selected from" the (S,R)- and (R,R)-isomers for the manufacture of a medicament for treating dyslipidemia; i.e. the single use of each isomer is included as well as mixtures thereof. It appears that now the a posteriori objection has been raised on the basis of absence of parallelism.

4. In the light of the prior art, the problem to be solved by the application is to provide a further medical use for the isomers of labetalol. At least as far as the EPO is concerned, subject to a correct formulation, such further medical uses are patentable (cf. decision of the Enlarged Board of Appeal, Gr 05/83, O.J. EPO, 1985, page 64).

The Applicant has demonstrated that both the (S,R)-(R,R)-isomers and mixtures thereof are suitable for solving the said problem, i.e. providing as a further medical use the treatment of dyslipidemia, and provide a basis for Claim 9 which has been drafted in accordance with Gr 05/83 referred to above.

Taking into account the new citations raised by the ISA, it appears that not only the (R,R)-isomer but also the (S,R)-isomer was known for a first medical use and, consequently, the claim to the pharmaceutical composition could not stand as in Claim 6, but the composition for the first medical use should be limited to the mixture of (S,R)- and (R,R)-isomers. The Board observes that this is precisely the subject-matter of Claim 7. No objection has been raised against this claim and the situation of non-parallism is of the same nature as that which initially existed between Claims 6 and 9 for which, correctly, no a priori objection had been raised (see Point 3 above). The Board considers that there is a prima facie unity of invention between a claim to the use of a mixture or its separate components for the manufacture of a medicament for a specific indication (second medical indication) and a claim to the mixture only as a pharmaceutical composition (first medical indication). In the present circumstances the situation which prevailed before the novelty objection still applies after it. The conditions of Rules 13.1 and 13.2 PCT are therefore satisfied and the additional fee should be reimbursed.

Order

For these reasons, it is decided that:

Refund of the additional search fee is ordered.

The Registrar: The Chairman:

M. Beer P. Lançon