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DECISION
of 20 December 2002

Case Number: W 0011/02 - 3.3.1
Application Number: PCT/IN 01/00005
Publication Number: -
IPC: C07D 207/00
Language of the proceedings: EN

Title of invention:

Compounds having hypolipidemic and hypocholesterolemic activities, process for their preparation and pharmaceutical compositions containing them

Applicant:

CADILA HEALTHCARE LTD
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Gujarat
India

Headword:

Propanoic acids/CADILA

Relevant legal provisions:

PCT Art. 17(3)(a)
PCT R. 13.1, 13.2, 40.1, 40.2
PCT Administrative Instructions, Annex B, Part 1, (g)(i)
and (v)

Keyword:

"Lack of unity *a posteriori* (yes) - intermediate not new -
disqualification as unifying element"

Decisions cited:

G 0001/89, W 0003/94, W 0006/94, W 0006/96

Catchword:

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International Application No. PCT/IN 01/00005

D E C I S I O N
of the Technical Board of Appeal 3.1.1
of 20 December 2002

Applicant: CADILA HEALTHCARE LTD
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Decision under appeal: Protest according to Rule 40.2(c) of the Patent Cooperation Treaty made by the applicants against the invitation (payment of additional fees) of the European Patent Office (International Searching Authority) dated 26 September 2001.

Composition of the Board:

Chairman: A. Nuss
Members: R. Freimuth
B. Günzel

Summary of Facts and Submissions

- I. Following the filing of international application No. PCT/IN 01/00005 the EPO, acting as ISA, on 26 September 2001 issued an invitation to pay within 45 days an additional search fee (Article 17(3)(a) and Rule 40.1 PCT).
- II. The said international application contained 19 claims. Claims 1 to 5 and 8 were directed to β -aryl- α -substituted propanoic acids having general formula (I) and claims 9 to 14 to the use of the latter compounds or to a pharmaceutical composition comprising those compounds, respectively. Claims 6 and 7 referred to processes for preparing the compounds of formula (I) starting *inter alia* from the compounds of formulae (1c) and (1e). Claims 15, 16 and 17 were directed to the intermediate compounds of formulae (1h), (1c) and (1e), respectively, and claim 18 to a process for preparing the compounds of formula (1h). Claim 19 related to a method for preparing the intermediate compounds of formulae (1c) and (1e) starting from the compound (1a).

The ISA stated in the invitation to pay additional fees (IPAF) that the international application related to two groups of inventions, namely:

group 1: claims 1 to 18 and

group 2: claim 19.

The ISA held that group 1 concerned the compounds of formula (I) useful in the treatment of several diseases, processes for their preparation and intermediate

compounds, while group 2 related to a further process for the preparation of compounds of formulae (1c) and (1e) which were already known from the following documents, the relevant passages therein being given in detail in the annexed search report:

- (1) EP-A-114 632,
- (2) EP-A-133 247,
- (3) GB-A-2 141 709,
- (4) US-A-4 229 352,
- (5) EP-A-41 711,
- (6) US-A-4 232 038,
- (7) US-A-4 410 534,
- (8) EP-A-163 559,
- (9) US-A-5 418 242,
- (10) WO-A-94/12165,
- (11) EP-A-507 696,
- (12) US-A-4 505 920,
- (13) US-A-3 980 089,
- (14) US-A-4 252 724,

(15) US-A-4 235 777 and

(16) US-A-4 224 330.

The second inventive concept was obviously different from the first one. There existed no technical feature which could be considered as to be common to both inventions. Both inventive concepts thus solved different technical problems in the sense of Rule 13.2 PCT. Therefore there was no single inventive concept underlying the plurality of claimed inventions of the present application. Consequently, there was a lack of unity.

III. On 28 January 2002 the Applicant paid the additional search fee under protest (Rule 40.2(c) PCT). In support of the protest the Applicant submitted that according to claim 6 compounds of *inter alia* formulae (1c) and (1e) were useful intermediates in the preparation of the compounds of formula (I). Regardless of whether the former were novel or known *per se*, the intermediates as well as the final compounds of formula (I) related to a single invention. It appeared that the only reason for holding claim 19 to be distinct was that the intermediates of formulae (1c) and (1e) were held to be known *per se*. However, they were not (entirely) known. Even if the compounds of formulae (1c) and (1e) were known, they would still not cease to be relevant for the preparation of the final compounds of formula (I). Rule 13.2 PCT, for establishing unity, required merely that a group of inventions should involve a "special technical feature". The technical contribution made in the preparation of compounds of formula (I) by the compounds of formulae (1c) and (1e) was very identical

to the technical contribution made by the intermediate of formula (1h). Similarly, claim 19 which was directed to the preparation of intermediates of formulae (1c) and (1e) made an identical technical contribution as did claim 18 which was directed to the preparation of intermediates of formula (1h).

The Applicant reiterated that the intermediates of formulae (1c) and (1e) were not entirely known as there was only certain overlapping with the prior art.

Therefore he might consider restrictions to claims 16 and 17 after receipt of the Written Opinion, formulated by way of example in the form of 15 disclaimers. The Applicant emphasised that none of the prior art document cited by the ISA anticipated **in entirety** claims 16 and 17 directed to the intermediates of formulae (1c) and (1e). Therefore the technical contribution of the invention claimed in claims 19, 18 and 16 and 17 was identical so that they were unitary with claims 1, 6 and their dependants, i.e. unity of invention existed between both groups of claims.

The Applicant requested that the additional search fee be refunded.

- IV. On 28 January 2002 the ISA's Review Panel informed the Applicant that, after having performed the prior review pursuant to Rule 40.2(e) PCT, it found the IPAF completely justified and invited the Applicant to pay the protest fee within one month. It confirmed the reasoning given in the IPAF and stated that the lack of unity lay in the finding that compounds of formulae (1c) and (1e) were known in the art. It followed that any further process for the preparation of such compounds

useful as intermediates in the preparation process of the end products of formula (I) did not make any technical contribution as far as the main inventive concept was concerned. The main inventive concept could not include processes for the preparation of known compounds since for the present overall preparation process it was possible simply to start from these known compounds of formulae (1c) and (1e). Consequently the provision of a further process for the preparation of known compounds represented a different inventive concept non-unitary with the main inventive concept. Reference was made to the Administrative Instructions under the PCT, Annex B, Part 1, (c)(ii) and (g)(v). Thus the present lack of unity was caused by the fact that individual compounds of formulae (1c) and (1e), to be prepared in the process of claim 19, were described in the prior art and, hence, not novel. There did not exist a common concept between claim 1 and claim 19. For this reason, non-unity existed between the subject-matter of these claims.

V. On 22 February 2002 the Applicant paid the protest fee.

Reasons for the Decision

1. The protest is admissible.
2. The communication containing the result of the prior review and inviting the Applicant to pay the protest fee does not reveal the composition of the Review Panel. Although this information should be available to the Applicant and to the Board in order to have a basis to see whether the review has been made by the appropriate

body as prescribed by the President of the EPO (see OJ EPO 1992, 547), such invitation is to be considered correct if the correct composition has been shown otherwise (see decision W 6/96, 15 April 1997, point 1 of the reasons). In the present case, the copy in the search file SA (E) 333 992 indicates the three members of the Review Panel and bears their signatures. Thus, that Review Panel was correctly composed and was competent for inviting to pay the protest fee.

3. The Applicant submitted that he might consider amendments to claims 16 and 17 after receipt of the Written Opinion and formulated by way of example 15 disclaimers to those claims.

The Board notes that the Applicant did not request to base the review proceedings and/or the protest proceedings on any amended claim 16 or 17. The Board observes nevertheless that it has no power anyway to examine the unity of present invention on the basis of any fresh claim as its powers derive from Article 154(3) EPC in conjunction with Rule 40.2(c) PCT which provide for it to examine exclusively the protest against the invitation by the ISA to pay an additional search fee. This the Board can only do on the basis of the claims present when the ISA issued said invitation; there is no provision for amendments during proceedings before the ISA (see decisions W 3/94, OJ EPO 1995, 775, point 3 of the reasons; W 6/94, point 4 of the reasons, not published in OJ EPO).

Therefore, the present decision is based on the claims as originally filed.

4. According to Rule 13.1 PCT, the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. If the ISA considers that the claims lack this unity, it is empowered to invite the Applicant to pay additional fees pursuant to Article 17(3)(a) PCT.

Lack of unity of invention 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 revealed by the search. Alternatively, the ISA is also empowered to raise that objection *a posteriori*, i.e. after having taken into account the state of the art revealed by the search (see decision G 1/89, OJ EPO 1991, 155). In the present case, the ISA raised the objection of non-unity based on the prior art documents (1) to (16) and was thus made *a posteriori*.

5. The objection of non-unity was based by the ISA on the ground that there is no common inventive concept linking the subject-matter of claims 1 to 18 (group 1) and that of claim 19 (group 2) since the intermediate compounds of formulae (1c) and (1e) common to both groups of claims are not novel. While the Applicant emphasized that both groups share the compounds of formulae (1c) and (1e), the Board, nonetheless, holds in the present case that the mere fact that those compounds are starting compounds in the preparation process of claim 6 of group 1 and that those compounds can be obtained by the process of claim 19 of group 2, is not in itself sufficient to establish unity of invention.

6. The ISA's conclusion is correct that numerous intermediate compounds of formulae (1c) and (1e) are disclosed in documents (1) to (16) at those passages specified in the search report annexed to the IPAF and that therefore compounds having these formulae are known in the prior art. This fact has been conceded indeed by the Applicant when submitting that the compounds of formulae (1c) and (1e) showed "certain overlapping with the prior art" and that these compounds were not known "in entirety" from the prior art. Hence, the compounds of formulae (1c) and (1e) cannot serve as a common inventive concept between claims 1 to 18 (group 1), on the one hand, and claim 19 (group 2), on the other. Furthermore, the technical problem to be solved by the second group of inventions was to provide an alternative to the known process for preparing compounds of formulae (1c) and (1e) (application page 23, lines 25 and 26), whereas the first group of inventions was intended to solve the different technical problem of providing novel β -aryl- α -substituted propanoic acids, their use, their pharmaceutical compositions, processes for their preparation and intermediates therein, as indicated in the application on page 1, lines 6 to 11.

According to Rule 13.2 PCT one and the same international application may relate to a group of inventions if there is a "technical relationship" among those inventions involving one or more of the same or corresponding "special technical features", i.e. such technical features that define a contribution which each of the claimed inventions makes over the prior art. However, a technical feature which already forms part of the prior art, as do compounds of formulae (1c) and (1e), cannot by definition make a contribution over the art

and therefore disqualifies as a unifying element in the sense of Rule 13.1 PCT. Thus, the fact that numerous compounds of formulae (1c) and (1e) are part of the prior art destroys the link between the contributions over the prior art made by the claimed invention according to group 1, on the one hand, and according to group 2, on the other.

For those reasons, in the circumstances of the present case, the Applicant's submission based on the compounds of formulae (1c) and (1e) fails to establish unity of invention for the present international application, as does the lack of any common technical problem underlying both groups of inventions.

7. The ISA relied moreover on the Administrative Instructions under the PCT to object to non-unity of the present international application.

Pursuant to Article 2 of the Agreement between the EPO and WIPO dated 7 October 1987 (OJ EPO 1987, 515) the international search shall be carried out in accordance with the Patent Cooperation Treaty, its Regulations and the Administrative Instructions; when carrying out the international search under the PCT, the International Search Guidelines shall guide it. Chapter VII-1 of those Search Guidelines stipulates that when assessing unity of invention in accordance with the provisions laid down in Rule 13.1 to 13.4 PCT, *inter alia* Annex B of the Administrative Instructions under the PCT are to be observed. It follows therefrom that in the assessment of unity the Administrative Instructions are binding not only for the ISA but also for the Board acting as the "three-member board" according to

Rule 40.2(c) PCT (see decisions G 1/89, *loc cit.*; W 3/94, *loc cit.*, point 10 of the reasons).

8. With respect to the unity of invention relating to the particular situation involving intermediate and final products, which is generally governed by Rule 13.2 PCT, the Administrative Instructions under the PCT stipulate in Part 1, (g)(v) of Annex B in particular that "the intermediate and final products shall not be separated, in the process leading from one to the other, by an intermediate which is not new" wherein the term "intermediate" is intended to mean intermediate or starting products, as defined in section (g)(i) of that Part 1.

In the present case, the compounds of formulae (1c) and (1e) are both, the product obtained in the preparation process of claim 19 of group 2, which starts from compound (1a), and the starting product in the process of claim 6 of group 1 for preparing the final β -aryl- α -substituted propanoic acids of formula (I) according to claim 1. Hence, the overall process leading from the starting compound (1a), which is an "intermediate" in the sense of Annex B, Part 1, (g)(i), via the compounds of formulae (1c) and (1e) to those final compounds of formula (I) represents "the process leading from one to the other" in terms of Annex B, Part 1, (g)(v) of the Administrative Instructions, the compound of formulae (1c) and (1e) being intermediates therein.

However, compounds of formulae (1c) and (1e) are disclosed in the prior art documents (1) to (16) and therefore not novel. Thus, in the overall process leading from one to the other, the starting and the

final products are separated by intermediates of formulae (1c) and (1e) which are not new, with the consequence that the requirements of unity of invention as set out in particular in Annex B, Part 1, (g)(v) of the Administrative Instructions are not satisfied. Thus, this instruction on non-unity governs in particular the present situation.

9. For the foregoing reasons, the Board comes to the conclusion that the inventions according to group 1 and group 2 are not part of a single general inventive concept and, consequently, that the invitation made under Article 17(3)(a) and Rule 40.1 PCT to pay one additional search fee was justified.

Order

For these reasons it is decided that:

The protest is dismissed.

The Registrar:

The Chairman:

N. Maslin

A. Nuss