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**European Patent  
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Boards of Appeal

**Office européen  
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Chambres de recours



**Case Number: W 05 / 85**

**International Application No PCT/EP 85/00171**

**DECISION**  
**of the Technical Board of Appeal 3.3.1.**  
**of 21 March 1986**

**Applicant:** SANDOZ AG  
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**Representative:** Norris, Allen E.  
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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 2 August 1985.

**Composition of the Board:**  
**Chairman:** K. Jahn  
**Member:** P. Lançon  
**Member:** G. Paterson

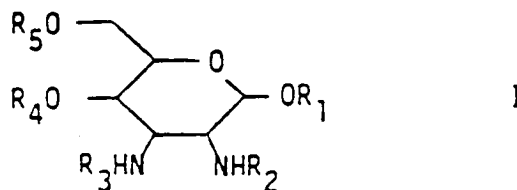
Summary of Facts and Submissions

- I. On 17 April 1985, the Applicants filed an international patent application PCT/EP 85/00 171 with the European Patent Office. The European Patent Office was designated Office within the meaning of Article 2 (xiii) PCT.
- II. On 2 August 1985, the European Patent Office as competent International Searching Authority issued, pursuant to Article 17(3)(a) PCT and Rule 40(1) PCT, an invitation to pay two additional search fees in view of the fact that it is considered that the above identified application did not comply with the requirements of unity of invention as set forth in Rule 13(1) PCT. It stated that Claims 1-9 were directed to compounds of formula I (as far as at least one of  $R_1$ ,  $R_4$  is a phosphor atom containing radical), pharmaceutical compositions containing them and a process for preparing them, but that Claims 1-3 and 7-9 were also directed to compounds of formula I (as far as neither  $R_1$  nor  $R_4$  is a phosphor atom containing radical), pharmaceutical compositions containing them and a process for preparing them, while Claim 10 related to intermediates of formula II (i.e. compounds not containing the "inventive part(s)" of the compounds of formula I).
- III. On 20 August 1985, the Applicants paid one additional search fee to cover one additional search directed to the second mentioned "invention". They paid this additional search fee under protest (Rule 40(2)(c) PCT) and asserted in a reasoned statement that the invention comprises a chemically clearly defined group of compounds possessing activity as pharmaceuticals. According to the Applicants, the fact that certain substituents are variable does not in any way affect the basic unity in the invention of a novel

class of pharmaceutically active substances. Therefore, they submit that the division of such a compound group according to substituent type is arbitrary and unjustified.

Reasons for the Decision

1. Pursuant to Article 154(3) EPC and Article 9 of the agreement between WIPO and the EPO, the Boards of Appeal of the EPO are responsible for deciding on protests made by an Applicant against an additional search fee charged by the EPO under the provisions of Article 17(3)(a) PCT. (O.J. EPO 4/1978, 249). Therefore, the protest, as it complies with Rule 40(2)(c) PCT 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 general inventive concept.
3. In the present case, the international patent application relates to
  - compounds of formula I

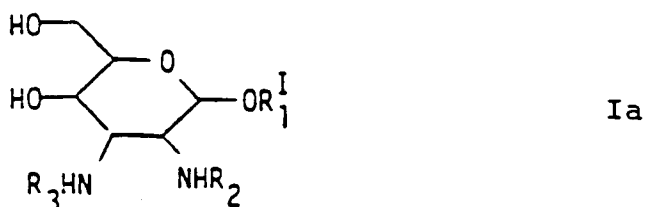


wherein  $R_2$  and  $R_3$  are the same or different and each represent unsubstituted or substituted acyl, and

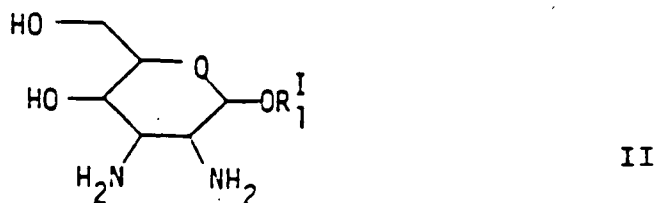
- (a)  $R_1$  represents lower alkyl, aralkyl or the phosphate, pyrophosphate, phosphorylethanolamine or pyrophosphorylethanolamine group,  $R_4$  represents the phosphate, pyrophosphate, phosphorylethanolamine or pyrophosphorylethanolamine group and one of  $R_1$  and  $R_4$  may additionally represent hydrogen and  $R_5$  represents hydrogen or a glycosyl radical or
- (b)  $R_1$  represents hydrogen, lower alkyl or aralkyl and  $R_4$  and  $R_5$  represent hydrogen in free form or when at least one of  $R_1$  and  $R_4$  represents a phosphorus bearing group with hydroxy, in the form of salts or esters (Claims 1 to 8),

- A process for preparing a compound of formula I according to Claim 1 in free form or in salt or ester form which comprises

- (a) to prepare compounds of formula Ia,

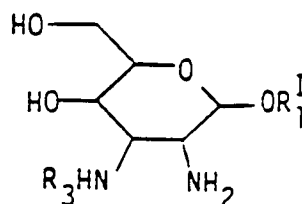


acylating the corresponding compound of formula II



whereby  $R_2$  and  $R_3$  are the same and are as defined above and  $R_1^I$  stands for hydrogen, lower alkyl or aralkyl,

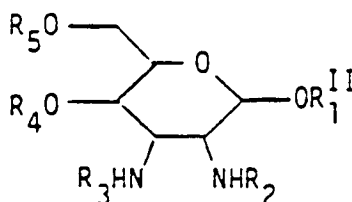
- (b) to prepare a compound of formula Ia wherein  $R_2$  and  $R_3$  are different acylating a compound of formula IIa,



IIa

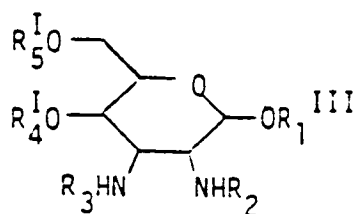
wherein  $R_1^I$  and  $R_3$  are as defined above or

- (c) to prepare a compound of formula Ib,



Ib

wherein  $R_2$  to  $R_5$  are as defined above and  $R_1^{II}$  represents hydrogen, lower alkyl, aralkyl or the phosphate, pyrophosphate, phosphorylethanolamine or pyrophosphorylethanolamine group whereby  $R_1^{II}$  and  $R_4$  are not simultaneously hydrogen, reacting a compound of formula Ic,



Ic

wherein  $R_2$  and  $R_3$  are as defined for formula I,  $R_1^{III}$  represents hydrogen, lower alkyl, aralkyl or a protecting group and

$R_4^I$  represents hydrogen or a protecting group whereby  $R_1^{III}$  and  $R_4^I$  are not simultaneously protecting groups, and  $R_5^I$  represents a protecting group or a glycosyl radical with a corresponding phosphorous compound and if required removing any protecting groups present in the compounds obtained and recovering the compound obtained in free form or in salt or ester form as appropriate (Claim 9), and

- A compound of formula II as hereinbefore defined (Claim 10).

4. The International Searching Authority in its Invitation dated 2 August 1985 has considered that the international application does not comply with the requirement of unity of invention as set forth in the Regulations. It distinguished three inventions, two of them being claimed by Claim 1 and the third one being claimed by Claim 10, and it invited the Applicants to pay two additional fees under Rule 40.1.

The Applicants by their letter dated 16 August 1985 protested against the invitation of the International Searching Authority, but they paid only one additional fee specifically to cover one additional search directed to the second invention, that is the second invention claimed by Claim 1. No additional fee has been paid for the third invention which is the subject-matter of Claim 10.

Under the circumstances, the Board is not concerned with the question of unity of invention relating to Claim 10 (Rule 40.2 (c) first sentence). Thus, the only question for the Board to examine is whether or not the protest in relation to Claim 1 is justified.

5. In the case of a protest under Rule 40(2) PCT, the only way to determine the technical problem (in contradistinction to the normal approach when considering inventive step - see T 01/80 "Carbonless copying paper" O.J. EPO 7/81, 206) is to rely on the description of the application. As it appears from the description, the problem was to find compounds useful as pharmaceutical agents, especially as immunostimulants (description page 1, lines 1 to 3).
6. Accordingly, the Applicants have found that the compounds of formula I as claimed in Claims 1 to 9 are useful as immunostimulants (description page 8, lines 1 to 3 and page 11 (lines 1 to 17)). Consequently, all such compounds must be considered as a solution to the problem.

All these compounds include a significant common structural element so that the unity of invention cannot be questioned *à priori*.

7. The file sent by the Searching Authority to the Board for the purpose of examination of the protest contains a list of chemical names submitted as a result of a search on line directed to the subject-matter of Claim 1.

In this long computer list of mere chemical names, five products can be recognised whose formula falls within the general formula I of the compounds claimed in Claim 1.

It appears clearly that the Searching Authority has based its objection of lack of unity relating to Claim 1 on the ground that the subject-matter of Claim 1 is lacking in novelty. However, the statement of reasons for lack of unity in the Invitation dated 2 August 1985 makes no reference to prior art or lack of novelty of Claim 1; and so, if such prior art was taken into account by the Searching Authority in making its objection of lack of unity, the Applicants have not been

so informed, and have not been given the opportunity to comment upon the basis for the Searching Authority's objection. In such a situation as a matter of principle the Board would not wish to uphold the finding of lack of unity of invention by the Searching Authority; at least not without first providing an opportunity for the Applicants to be informed of and to comment upon the full reasoning of the Searching Authority.

8. In the present case, however, even on the assumption that the Searching Authority has used loss of novelty as the basis for its finding of a lack of a single inventive concept as required by Rule 13(1) PCT, after examining the facts of the case, the Board cannot support this view, for the following reasons.
9. In the first instance, concerning the list of chemical names present in the file, the Board states that such list contains neither sufficient technical information relating to the named products nor the date nor the nature of the documents. No evidence is submitted that these products, merely named, correspond in fact to relevant prior art. On this basis alone, the assumed basis for the Searching Authority's objection must be considered unsound.

In the present case, it could have been important to know whether the five named products correspond to specific disclosures of specific compounds per se, or whether they are illustrative examples, in the original disclosures, of one group of compounds.

10. Furthermore, even on the assumption that the general formula I of Claim 1 is not new, in application of the well established principle that a specific disclosure within the claim takes away the novelty of a generic claim embracing



this disclosure, the loss of novelty, by such a specific disclosure does not necessarily result in loss of unity. The Board in fact cannot support the finding of lack of unity in this case, for the reasons which follow.

The Board considers that an invention is unitary when there is a single underlying technical problem and when the means proposed to solve it belong to a single inventive concept - this is the case here, as the common technical problem was to find compounds useful as pharmaceutical agents, especially as immunostimulants, and such problem has been solved by compounds which are technically interconnected by a common structural feature, irrespective of whether or not they contain phosphorus.

In the description and in the claims, a significant number of examples of such compounds with or without a phosphor-atom containing radical is given (see for instance Claim 5). Further, the description mentions preferred compounds, e.g. compounds of formula I, wherein at least one of  $R_1$  and  $R_4$  represents a phosphate, pyrophosphate, phosphorylethanolamine or pyrophosphorylethanolamine radical.

Faced with an objection of lack of novelty (Article 54 CBE) based upon the prior disclosure of 5 specific compounds within the general formula I, the Applicants have various possibilities of restricting their claims during the later procedure, without jeopardising the unity of the invention. The restricted subject-matter is normally defined on the basis of the dependant claims or of the examples. Alternatively, in certain circumstances, the Board has already allowed the use of disclaimers, (T 04/80 "Bayer/Polyether polyols" OJ EPO 4/82, 149; T 188/83 "Vinyl acetate/FERNHOLZ" OJ EPO 11/84, 555).

On the other hand, there may be cases in which the use of disclaimers could lead to questioning the unity of invention. For instance, if the disclaimer has such an extent that the subject-matters remaining in the claim are structurally far from each other. These questions have not been examined at present.

It follows that an objection of lack of novelty of a chemical general formula does not necessarily lead to an absence of unity, as long as a single general inventive concept is maintained for the restricted subject-matter after amendment so as to overcome the lack of novelty objection. This would appear to apply in the present case. Thus the requirement of unity of invention in Rule 13(1) PCT is met. Consequently, the invitation to pay an additional fee dated 2 August 1985 was unjustified. The protest is thus allowable.

Order

For these reasons it is decided that:

the reimbursement to the Applicants of the additional fee is ordered.

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*HT*

*Rue*

*W. M.*