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Aktenzeichen / Case Number / N° du recours : T 81/84

Anmeldenummer / Filing No / N° de la demande : 80 900 811.3

Veröffentlichungs-Nr. / Publication No / N° de la publication : 26 221

Bezeichnung der Erfindung: Dysmenorrhoea treatment

Title of invention:

Titre de l'invention :

Klassifikation / Classification / Classement :

### ENTSCHEIDUNG / DECISION

vom / of / du 15 May 1987

Anmelder / Applicant / Demandeur : William H. Rorer, Inc.

Patentinhaber / Proprietor of the patent /  
Titulaire du brevet :

Einsprechender / Opponent / Opposant :

Stichwort / Headword / Référence : "Dysmenorrhoea"

EPÜ / EPC / CBE Article 52(1), 52(4) and 54(5) EPC

Kennwort / Keyword / Mot clé : "Therapy - Treatment of pain, discomfort  
and incapacity" - "Second medical  
indication"

#### Leitsatz / Headnote / Sommaire

"Irrespective of the origin of pain, discomfort or incapacity, its relief, by the administration of an appropriate agent, is to be construed as "therapy" or "therapeutic use" in the sense of Article 52(4) EPC, and must be considered in the light of the decision of the Enlarged Board of Appeal in respect of claims directed to the use of a substance or composition for the manufacture of a medicament for a specified, new and inventive therapeutic application (Gr 05/83, "Second medical indication", OJ 3/1985, 64).

Europäisches  
Patentamt

Beschwerdekammern

Case Number : T 81/84

European Patent  
Office

Boards of Appeal

Office européen  
des brevets

Chambres de recours



**D E C I S I O N**  
of the Technical Board of Appeal 3.3.2  
of 15 May 1987

**Appellant :** WILLIAM H. RORER, INC.  
500 Virginia Drive  
Fort Washington, PA 19034  
U.S.A.

**Representative :** Sanderson, Laurence Andrew  
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**Decision under appeal :** Decision of Examining Division 001 of  
the European Patent Office  
dated 7 November 1983 refusing European  
patent application No. 80 900 811.3  
pursuant to Article 97(1) EPC

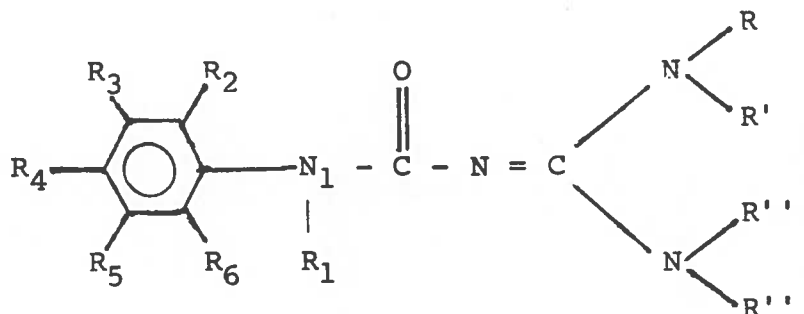
**Composition of the Board :**

**Chairman :** P. Lançon  
**Member :** G. Szabo  
**Member :** O. Bossung

Summary of Facts and Submissions

I. European patent application No. 80 900 811.3, filed on 2 April 1980 as PCT International Application No. PCT/US 80/00 344 was refused by decision of the Examining Division of the EPO dated 7 November 1983. This decision was based on 12 claims. Independent Claims 1 and 8 were as follows:

"1. A method for relieving the discomfort of a human female attendant to menstruation, which method comprises administering thereto an effective amount of an amidino-urea of the general formula:



where:

R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, R<sub>5</sub> and R<sub>6</sub> may be the same or different and are: hydrogen, halo, lower alkyl, halo lower alkyl, nitro, lower alkoxy, hydroxy, aryl-lower alkoxy, acyloxy, cyano, halo lower alkoxy, or lower alkyl sulfonyl;

R and R' are hydrogen or lower alkyl;

R'' and R''' are: hydrogen, lower alkyl, lower alkoxy, lower alkenyl, cyclo alkenyl up to 9 carbon atoms, cyclo alkyl lower alkyl, lower alkyl, cyclo alkyl, aralkyl, lower alkynyl, halo alkyl, hydroxy alkyl, alkoxy alkyl, cyano alkyl, amino alkyl, mono- and di-lower alkyl amino alkyl, carbamoyl alkyl, mono- and

di- carbamoyl alkyl, carboxy alkyl, alkoxy carbonyl alkyl, aralkoxy carbonyl alkyl, formyl, acyl, acylalkyl, alkyl sulfonyl, or aralkyl sulfonyl; R" and R"' together may form a 5 to 7 atom ring which may include 0 to 2 hereto atoms of N, O or S; R<sub>1</sub> is hydrogen or lower alkyl, provided at least one of R, R', R" and R"' is other than hydrogen; and the pharmaceutically acceptable salts thereof.

8. A composition for use in relieving the discomfort of a human female attendant to menstruation, which composition is in a solid unit dosage form and comprises from about 5 mg to about 10 mg of an amidino-urea of the general formula I or a salt thereof as defined in Claim 1, together with an excipient, diluent or carrier."

II. The grounds for refusing the application were that relieving the discomfort of a human female attendant to menstruation according to Claim 1 must be regarded as a method of treatment of the human body by therapy and thus not allowable under Article 52(4) EPC, and that the subject-matter of Claim 8, directed to a composition, was not novel in respect of Article 54(5) EPC, since the same had already been known for use in therapy. The method claims were also unallowable under Article 57 EPC as not industrially applicable and essentially biological.

III. The Appellant (former Applicant) lodged an appeal against the decision on 5 January 1984 by telex message (confirmed on 14 January 1984) and paid the appeal fee on 9 January 1984. A Statement of Grounds was filed on 6 March 1984, with additional claims. A Communication from the Board, dated 12 June 1984, informed the Appellant that in view of the proceedings before the Enlarged Board of Appeal concerning the fundamental question of the patentability

of therapeutic treatments of the human body, the consideration of the issues of the present appeal were suspended until the Enlarged Board resolved that question.

IV. In its decision Gr 05/83 of 5 December 1984 ("Second medical indication", OJ 3/1985, 64) the Enlarged Board of Appeal decided that a European patent may not be granted with the above kind of method or use claims but may be granted with claims "directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application".

V. The Appellant thereafter filed a new additional claim to such use. The Board objected to all method and composition claims as unallowable in principle except the newly filed claim in accordance with the decision of the Enlarged Board of Appeal. In compliance with the Board's request all other claim categories were deleted and the new use claim, directed to the preparation of the medicament, and supplemented with subsidiary claims of narrower scope, was presented in the letter from the Appellant dated 29 January 1987 for consideration. Claim 1 is as follows:

"Use of an amidino-urea of the general formula:

(I)..... (as defined in the above original method claim)  
.... for the manufacture of a medicament for use in relieving the discomfort of a human female attendant to menstruation or in the treatment of associated disorders such as endometriosis".

VI. The arguments of the Appellant in the Statement of Grounds have become irrelevant in view of the abandonment of all categories of claims on which the decision of refusal was based. The conduct of the Appellant, solely relying on the

kind of claim introduced by the Enlarged Board relating to the preparation of medicaments for use in therapy, also implies that the submissions, concerning the alleged non-therapeutic character of discomfort associated with menstruation, are no longer pursued either.

VII. The Appellant requests that the decision of the Examining Division be set aside and the matter be remitted on the basis of Claims 1 to 7 on file for substantive examination to the Examining Division.

#### Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 64 EPC and is, therefore, admissible.
2. No basic formal objections are raised in relation to the main claim on file, since this is generally supported by former Claim 1 as originally filed and by other statements concerning dysmenorrhea and endometriosis in the specification. The exact wording of this and subsequent subsidiary claims may, of course, depend on other considerations in the forthcoming substantive examinations as well. In view of the decision of the Enlarged Board of Appeal clarifying the legal position and creating a new type of claim for invention of this nature, the disclosure and the claims may be redrafted in conformity with Article 123(2) and Rule 86(3) EPC during prosecution.
3. Nevertheless, the question arises whether or not the character of menstrual discomfort manifesting itself for instance in intensive headaches and other painful symptoms is such that its treatment should fall under the category of therapeutic treatment. In the view of the Board, the concept of therapy should not be confined narrowly. There are many chemical agents which are used by physicians to

relieve pain, discomfort and incapacity. Although at least some of such and similar experiences may have been caused by natural circumstances (e.g. menstruation, pregnancy or age etc.) or by a reaction to situations in the human environment (e.g. atmospheric conditions provoking tiredness, headaches, etc.), these overlap with and are often indistinguishable from symptoms of a disease or an injury. The biochemical effects and mechanisms which medicaments generate in order to restore the normal, capable and painless state for the body are often very similar or identical in these instances and in cases of diseases, irrespective of the nature of the real cause.

4. It would be impossible and undesirable to distinguish between basic and symptomatic therapy, i.e. healing or cure and mere relief. The use of medicaments may be called for whenever the human body is suffering from a disease, illness, pain or discomfort or incapacity, and the administration thereof could provide or contribute to either full or partial healing, or relief or restoration of fitness. These are part of the everyday therapeutic activities of the medical profession, in addition to surgery and diagnostic methods also mentioned in Article 52(4) EPC. Contrary to other situations where the boundaries with the non-medical handling of the human body are not at all clear in view of the involvement of different specialists (e.g. cosmeticians), the treatment of pain normally is a matter exclusively reserved for the physician.
  
5. For these reasons it is the view of the Board that irrespective of the origin of pain, discomfort or incapacity, its relief, by the administration of an appropriate agent, is to be construed as "therapy" or "therapeutic use" in the sense of Article 52(4) EPC, and must be considered in the light of the decision of the

Enlarged Board of Appeal in respect of claims "directed to the use of a substance or composition for the manufacture of a medicament for a specified, new and inventive therapeutic application".

Order

For these reasons, it is decided that:

1. The contested decision is set aside.
2. The case is remitted to the Examining Division for further prosecution on the basis of Claim 1 to 7 submitted with letter dated 4 April 1986.

The Registrar:

The Chairman:

J. Ruckerl

P. Lançon