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D E C I S I O N
of 11 July 1994

Case Number: T 0055/91 - 3.3.2

Application Number: 85202050.2

Publication Number: 0186241

IPC: A61K 31/485

Language of the proceedings: EN

Title of invention:
Hydrocodone/ibuprofen pharmaceutical compositions and method

Applicant:
Arnold, John D.

Opponent:
-

Headword:
Analgesic composition/ARNOLD

Relevant legal norms:
EPC Art. 54, 113(1) and 116
EPC R. 71(1) and (2)

Keyword:
"Oral proceedings - non-attendance notified despite negative communication attached to summons - hearing held in the absence of Appellant - opportunity to comment not used"
"Novelty (no)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0055/91 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 11 July 1994

Appellant: Arnold, John D.
635 East 45th Street
Kansas City, Missouri (US)

Representative: Madgwick, Paul Roland
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Decision under appeal: **Decision of the Examining Division of the European Patent Office dated 25 June 1990, posted on 10 August 1990 refusing European patent application No. 85 202 050.2 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: P. A. M. Lançon
Members: A. J. Nuss
S. C. Perryman

Summary of Facts and Submissions

1. European patent application No. 85 202 050.2 was refused by a decision of the Examining Division for the reason that the subject-matter of the claims filed on 10 April 1989 did not involve an inventive step.

The claims for the Contracting States other than Austria were worded as follows:

"1. Use of a composition, comprising one part by weight of hydrocodone or a pharmaceutically acceptable acid addition salt thereof and about 20 to 80 parts by weight of ibuprofen or a pharmaceutically acceptable salt thereof, for preparing a pharmaceutical for treating pain.

2. A pharmaceutical composition comprising a pharmaceutically acceptable carrier and an analgesically effective amount of:

(a) one part by weight of an analgesic agent selected from the group consisting of hydrocodone and pharmaceutically acceptable acid addition salts thereof, and

(b) about 20 to 80 parts by weight of ibuprofen or a pharmaceutically acceptable salt thereof.

3. Use of a composition comprising a dosage unit containing about 5 to 10 mg of hydrocodone or a pharmaceutically acceptable acid addition salt thereof and about 200 to 400 mg of ibuprofen or a pharmaceutically acceptable salt thereof, for preparing a pharmaceutical for treating pain.

4. A pharmaceutical composition in unit dosage form comprising a pharmaceutically acceptable carrier and

(a) about 5 to 10 mg of an analgesic agent selected from the group consisting of hydrocodone and pharmaceutically acceptable acid addition salts thereof, and

(b) about 200 to 400 mg of ibuprofen or a pharmaceutically acceptable salt thereof."

A single process claim was filed for Austria on the basis of claim 1 for the Contracting States other than Austria.

II. In its decision, the Examining Division took the view that although the claims were novel, it was obvious to prepare a composition such as that mentioned in these claims in view of the teaching of document (1) EP-A-O 68 838 when read in the light of the information contained in (2) Martindale, The Extra Pharmacopoeia, 28th Edition - 1982 and (5) Goodman and Gilbert's "The Pharmacological Basis of Therapeutics", since 15 parts of morphine sulphate had to be regarded as corresponding to 11.28 parts of morphine base, as shown in the annex to the summons to oral proceedings.

In the absence of any evidence that the present compositions showed either an unexpected high synergetic effect or reduced side-effects, the presence of an inventive step had to be denied.

III. The Appellants lodged an appeal against this decision.

In the subsequent written proceedings before the Board, they argued in essence that in document (1) not only the ratios of ibuprofen to hydrocodone referred to were significantly different from those of the present claims but that there was also no direction in this document that would lead the skilled man to take the step of increasing the amount of ibuprofen present as compared to hydrocodone that the Examining Division deduced to be implied by example 12, so that it would not have been obvious to use substantially more narcotic for a given amount of ibuprofen than required in the claims. The data set out in the test reports clearly established the surprising properties of the present compositions as compared with those of document (1).

IV. In a communication pursuant to Article 11(2) of the Rules of procedure of the Boards of Appeal, posted on 5 May 1994 together with the summons to oral proceedings pursuant to Article 116 and Rule 71(1) EPC, the provisional opinion was expressed inter alia that given the teaching in example 12 of document (1) to substitute the amount of morphine mentioned in example 1 of that document by an equi-analgesic amount of hydrocodone, it would seem that document (1) disclosed at least one composition falling under the scope of present Claims 1 and 2. This followed from the explicit statement in example 1 that "Using the procedure above, capsules are similarly prepared containing morphine sulphate in 7.5 and 3.75 mg amounts by substituting 7.5 and 3.75 mg of morphine sulphate for the 15 mg used above. **These capsules are used to reduce the narcotic dose of the preceding examples**". When applying the calculations made by the Examining Division on the basis of document (5), i.e. The Pharmacological Basis of Therapeutics (Goodman and Gilman), for determining the equi-analgesic amount of hydrocodone to be used instead

of morphine sulphate, a composition containing 3.75 mg morphine sulphate appeared to correspond to one containing 1.41 mg of hydrocodone which in view of the unchanged ibuprofen content of 50 mg led indeed to a ratio ibuprofen: hydrocodone of 35,46:1.

V. In a telefax dated 8 July 1994, the Appellants' representative informed the Board that they "have today received instructions from the applicant that they do not wish to proceed with the oral proceedings on Monday, July 11, 1994. This is therefore to advise you that we will not be in attendance on that date".

VI. Oral proceedings were held on 11 July 1994 in the absence of the Applicants.

VII. The Appellants had requested, in writing, that the decision under appeal be set aside and that a patent be granted on the basis of the claims filed by letter of 10 April 1989.

Reasons for the Decision

1. The appeal is admissible.

2. The Appellants have had, in accordance with Article 113(1) EPC, an opportunity to present their comments on the detailed novelty objection raised in the Board's communication of 5 May 1994, but have not availed themselves of this opportunity.

3. On considering the case at the oral proceedings, duly held pursuant to Rule 71(2) EPC despite the absence of the Appellants, the Board came to the conclusion that

the subject-matter of Claims 1 and 2 lacked novelty in view of (1) for the reasons already set out in detail in the communication of 5 May 1994 (see point IV above).

4. It follows that the Appellants' request must fail as not complying with the requirements of Article 54 EPC, and the appeal must be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

P. Martorana P. A. M. Lançon