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# Datasheet for the decision of 20 May 2008

**Case Number:** T 0970/05 - 3.3.02

**Application Number:** 99930357.1

**Publication Number:** 1094817

**IPC:** A61K 31/52

**Language of the proceedings:** EN

**Title of invention:**
Compositions comprising GABA analogs and caffeine

**Patentee:**
Warner-Lambert Company LLC

**Opponent:**
-

**Headword:**
GABA analogs and coffeine/WARNER-LAMBERT COMPANY LLC

**Relevant legal provisions:**
EPC Art. 56

**Relevant legal provisions (EPC 1973):**
-

**Keyword:**
"Inventive step - no"
"Obvious combination"

**Decisions cited:**
-

**Catchword:**
-

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**Case Number: T 0970/05-3.3.02**

# D E C I S I O N
**of the Technical Board of Appeal 3.3.02**
**of 20 May 2008**

**Appellant:** Warner-Lambert Company LLC
235 East 42nd Street
New York, NY 10017 (US)

**Representative:** Rudge, Andrew john
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Ramsgate Road
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**Decision under appeal:** **Decision of the Examining Division of the European Patent Office posted 21 February 2005 refusing European application No. 99930357.1 pursuant to Article 97(1) EPC.**

**Composition of the Board:**

**Chairman:** U. Oswald
**Members:** J. Riolo
P. Mühlens

## Summary of Facts and Submissions

I. European patent application No. 99 930 357.1 entitled "compositions comprising GABA analogs and caffeine" was refused by a decision of the Examining Division dated 13 December 2004 on the grounds of lack of inventive step.

II. The following documents, cited during the proceedings before the Examining Division and the Board of appeal, remain relevant for the present decision:

(3) WO 98/07447
(4) The Clinical Journal of Pain 1997; 13; 251-255
(5) WO 98/17627
(6) WO 97/22853
(7) WO 95/07079
(8) US 4,656,177

III. The decision was based on claims 1 to 26 of the request filed on 20 November 2002.

Independent claim 1 of this request read as follows:

"1. Use of
(a) an analgesically effective amount of a GABA analog; and
(b) an effective amount of caffeine
for the preparation of a pharmaceutical composition for eliciting an enhanced analgesic response in a mammal."

IV. The arguments in the decision may be summarised as follows:

The problem to be solved by the application in suit concerned the improvement of the treatment of pain.

According to the claims, this problem was solved by a composition comprising GABA (gamma-aminobutyric acid) analogs and caffeine.

Having regard to the disclosure in documents (3), (4), (5) and (6), GABA analogs appeared to be well-known in the art to treat pain.

As documents (7) and (8) disclosed that caffeine enhanced the analgesic activity of known drugs, the Examining Division concluded that it was obvious to combine both drugs to solve the problem of improving the treatment of pain.

V. The appellant (applicant) lodged an appeal against the said decision.

VI. In a communication dated 20 December 2007, the appellant informed the Board that it would not attend the oral proceedings and would not be making any further written submissions or amendments.

VII. Oral proceedings were held before the Board on 20 May 2008.

VIII. The appellant's written submissions can be summarised as follows:

It stressed the advantages of using the GABA compounds, especially gabapentin and pregabalin, in the invention in question, i.e. their relatively non-toxic nature, their ease of preparation, the fact that they are well-tolerated, and their ease of administration (owing to the use of two active compounds for the preparation of a pharmaceutical).

It also pointed out that especially gabapentin had few interactions with major classes of drugs since it was not metabolized in the liver but rather excreted unchanged from the body.

Moreover, it submitted that the European Patent Convention contained no provision requiring an applicant to show that an invention solves a technical problem. In fact, the European Patent Convention required only that an invention must be novel, inventive and susceptible of industrial application.

It further added that experimental data should only be required where the Examining Division had evidence that a claimed compound does not comply with a provision of the EPC, such as where the use disclosed for a claimed compound is scientifically incredible, or where a claimed compound is found to be *prima facie* obvious for the disclosed use.

IX. The appellant requested in writing that the decision under appeal be set aside and that the patent be

granted on the basis of claims 1 to 26 of the request filed 20 November 2002.

## Reasons for the Decision

1. The appeal is admissible.

2. Inventive step

2.1.1 The Board considers that document (4), which discloses the use of a GABA compound (gabapentin) for the treatment of pain, can be considered as the closest state of the art (page 252, right column, third sentence under "Results"; page 254, left column, first paragraph under "Discussion").

The application states that the class of GABA pain relievers can provide improved efficacy when combined with caffeine (page 5, lines 2 to 5).

Therefore, starting from document (4), the technical problem to be solved is that of improving the efficacy of the analgesic GABA drugs.

The proposed solution is the subject-matter of independent claim 1, which involves the use of caffeine.

From the description, the Board is prima facie satisfied that the problem is plausibly solved.

The question to be answered is thus whether the proposed solution, i.e. the use of caffeine, is obvious to the skilled person faced with the problem defined

above in the light of the available prior art documents.

In that respect, documents (7) and (8) teaches that caffeine enhances the analgesic response of non-narcotic analgesics and of NSAID (Non-Steroidal Anti-Inflammatory Drug) analgesics ((7) page 2, lines 34 to page 3, line 4, and pages 3, lines 31 to 37; (8) page 6, right-hand column, lines 42 to 53, and page 7, left-hand column, lines 38 to 57).

Having regard, on the one hand, to the disclosure in document (4) with respect to the use of GABA drugs in the treatment of pain and, on the other hand, to documents (7) and (8), which teach that caffeine enhances the analgesic response of analgesics, the Board is convinced that the skilled person, faced with the problem as defined above, would consider the use of caffeine as a promising solution to the above-mentioned problem.

2.1.2 In its grounds of appeal, the appellant stressed the various advantages linked to the use of GABA drugs (see point VIII above, paragraphs 2 and 3).

The Board does not contest these advantages.

However, as they are inherent properties of GABA drugs and not the result of the claimed combination with caffeine, these advantages are not relevant for the assessment of inventive step in the present case, i.e. in answering the question whether the skilled person would have envisaged the combination of GABA drugs with caffeine with the expectation of an improvement in the therapy of pain.

Neither does the Board disagree with the appellant that the European Patent Convention contains no provision requiring an applicant to show that an invention solves a technical problem and that it only requires that an invention must be novel, inventive and susceptible of industrial application.

Article 56 does, however, require that the "invention" shall not be obvious to the skilled person in the art, having regard to the state of the art; this appears not to be the case here since, as discussed above, the claimed combination is rendered obvious in the light of documents (4) and (7) or (8).

As to the last point raised by the appellant in the grounds of appeal, it is correct that experimental data showing unexpected effects may be needed for the assessment of inventive step where a claimed subject-matter is found to be prima facie obvious. In that respect, the Examining Division was in fact right to invite the appellant to provide such evidence as it had shown that, in the light of the prior art, the claimed combination was prima facie obvious for the disclosed use (Examining Division's notification dated 15 May 2002).

For these reasons and in the absence of any evidence demonstrating any unexpected effects/properties of the "combination", the Board concludes that the subject-matter of claim 1 lacks an inventive step as required by Article 56 EPC.

Under these circumstances, there is no need to consider the remaining claims.

## Order

## For these reasons it is decided that:

The appeal is dismissed.

The Registrar | The Chairman

N. Maslin | U. Oswald