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**D E C I S I O N**  
**of 7 August 2002**

**Case Number:** T 0597/01 - 3.3.2

**Application Number:** 95931016.0

**Publication Number:** 0778770

**IPC:** A61K 31/485

**Language of the proceedings:** EN

**Title of invention:**

Composition alleviating pain, containing a non-narcotic analgesic and an analgesia enhancer

**Applicant:**

VIRGINIA COMMONWEALTH UNIVERSITY

**Opponent:**

-

**Headword:**

Composition alleviating pain/VIRGINIA UNIVERSITY

**Relevant legal provisions:**

EPC Art. 54

**Keyword:**

"Novelty (yes)"

"Subject-matter of the main request restricted over the prior art"

**Decisions cited:**

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**Catchword:**

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Case Number: T 0597/01 - 3.3.2

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.2  
of 7 August 2002

**Appellant:** VIRGINIA COMMONWEALTH UNIVERSITY  
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Virginia 23298 (US)

**Representative:** Kolb, Helga, Dr. Dipl.-Chem.  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 18 October 2000  
refusing European patent application  
No. 95 931 016.0 pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** P. A. M. Lançon  
**Members:** J. Riolo  
C. Rennie-Smith

## Summary of Facts and Submissions

- I. European patent application No. 95 931 016.0 published as WO 96/07412 under the Patent Cooperation Treaty (Article 158(1) EPC) was refused by a decision of the Examining Division posted on 18 October 2000 on the grounds of lack of novelty.
- II. The decision was based on the set of 11 claims filed on 5 May 2000. Independent claims 1 and 9 read as follows:
- "1. Use of
- (a) an analgesic inducing amount of acetaminophen and/or a non-steroidal, anti-inflammatory drug (NSAID), and
- (b) an analgesic-enhancing amount of at least one analgesia enhancer selected from the group consisting of dextromethorphan, dextrorphan, and pharmaceutically acceptable salt thereof
- in a method for formulating a composition for alleviating pain in a mammal exhibiting a pain condition but not exhibiting a cold, influenza, cough, mouth pain and/or dysmenorrhea condition, characterized in that analgesia enhancer (b) potentiates the analgesic effectiveness of acetaminophen and/or NSAID (a)."
- "9. A therapeutic composition comprising
- (a) at least one of dextromethorphan, dextrorphan and pharmaceutically acceptable salt thereof and

(b) at least one non-narcotic analgesic which is acetaminophen and/or a non-steroidal, anti-inflammatory drug (NSAID), selected from the group consisting of aspirin, diclofenac, diflusal, etodolac, fenbufen, fenoprofen, flufenisal, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, meclofenamic acid, mefenamic acid, nabumetone, oxaprozin, phenylbutazone, piroxicam, sulindac, tolmetin, zomepirac, and pharmaceutically acceptable salts thereof,

characterized in that said composition is formulated to comprise an analgesia-inducing amount of (b) said non-narcotic analgesic and an analgesia enhancing amount of (a) dextromethorphan, dextrorphan or pharmaceutically acceptable salt thereof potentiating analgesic effectiveness of (b) said non-narcotic analgesic."

III. The following documents were cited inter alia during the proceedings before the Examining Division and during the written proceedings before the Board of Appeal:

- (1) US-A-4 446 140
- (2) EP-A-0 529 898
- (3) EP-A-0 081 823
- (4) US-A-5 164 398.

IV. According to the text of the decision under appeal, the Examining Division was of the opinion that the compositions described in documents (1), (3) and (4) for the treatment of pain anticipated the subject-

matter of claim 9 and its dependent claim 10 of the application in suit.

- V. The appellant (applicant) lodged an appeal against this decision and requested that the decision under appeal be set aside and that the patent be granted on the basis of one the three sets of claims filed on 22 February 2001.

According to the appellant, the amended product claims were novel over the available prior art document because they were now limited to NSAIDs not shown in references (1) to (4).

- VI. The appellant filed on 25 July 2002 a new set of claims 1 to 10 as new main request.

Independent claims 1 and 4 read as follows:

- "1. A therapeutic composition comprising
- (a) an analgesia-inducing amount of at least one non-narcotic analgesic which is a non-steroidal, anti-inflammatory drug (NSAID) selected from the group consisting of diclofenac, diflusal, etodolac, fenbufen, fenoprofen, flufenisal, flurbiprofen, ketoprofen, ketorolac, meclofenamic acid, mefenamic acid, nabumetone, oxaprozin, phenylbutazone, piroxicam, sulindac, tolmetin, zomepirac, and pharmaceutically acceptable salts thereof,
  - (b) an analgesia enhancing amount of at least one of dextromethorphan, dextrorphan or pharmaceutically acceptable salt thereof potentiating analgesic

effectiveness of the non-narcotic analgesic (a)."

"4. Use of

(a) an analgesia-inducing amount of at least one non-narcotic analgesic which is a non-steroidal, anti-inflammatory drug (NSAID) selected from the group consisting of diclofenac, diflusal, etodolac, fenbufen, fenoprofen, flufenisal, flurbiprofen, ketoprofen, ketorolac, meclofenamic acid, mefenamic acid, nabumetone, oxaprozin, phenylbutazone, piroxicam, sulindac, tolmetin, zomepirac, and pharmaceutically acceptable salts thereof,

(b) an analgesia enhancing amount of at least one of dextromethorphan, dextrorphan or pharmaceutically acceptable salt thereof potentiating analgesic effectiveness of the non-narcotic analgesic (a),

for formulating a composition for alleviating pain in a mammal exhibiting a pain condition but not exhibiting a cold, influenza, cough, mouth pain and/or dysmenorrhea condition."

VII. The appellant requested that the decision under appeal be set aside and that the case be remitted to the first instance on the basis of the set of claims 1 to 10 filed on 22 July 2002.

## Reasons for the Decision

1. The appeal is admissible.

2. *Main request*

2.1 Article 123(2) EPC

Independent claim 1 is based on claim 18 in combination with the feature of its dependent claim 22 as originally filed. Moreover, three substances have been deleted from the list of the selected NSAIDs.

Its dependent claims 2 and 3 are based on claims 25 and 23 as originally filed respectively.

Independent claim 4 corresponds to claim 1 which is now labelled as a second medical use claim. It is based on claim 1 as originally filed in combination with the features of its dependent claims 3, 4 and 14 as originally filed. Moreover, three substances have been deleted from the list of the selected NSAIDs.

Its dependent claims 5 to 10 are respectively based on claims 6, 10, 11, 15, 16 and 1 as originally filed.

Consequently the requirements of Article 123(2) EPC are met.

2.2 Novelty

Document (1) discloses administering dextromethorphan (DM), optionally with ibuprofen, aspirin, acetaminophen, indomethacin or naproxen exclusively for the treatment of mouth pain (column 1, lines 49 to 55).

Document (2) relates to enhancing the antitussive effectiveness of DM by administering an antitussive amount of DM with an antitussive-potentiating amount of acetaminophen (page 2, lines 47 and 48).

Document (3) concerns the treatment of pain caused by dysmenorrhea, using aspirin, acetaminophen, indomethacin, naproxen or ibuprofen together with DM (claims 8 and 9).

Document (4) discloses a specific pharmaceutical composition comprising an analgesia/anti-inflammatory effective amount of ibuprofen and an antitussively effective amount of DM which is useful for pain treatment associated with cough, cold and flu (column 1, lines 48 to 60, column 2, lines 60 to 63).

As to the novelty of claim 1, which is drafted as a first medical use claim, the Board notes that none of the combinations disclosed in documents (1) to (4) for a medical treatment falls under the subject-matter of this claim.

Therefore the combinations of claim 1 are novel over the available prior art documents. This applies also to its dependent claims 2 and 3 and to the use claims 4 to 10 which involve the application of the novel combinations according to claim 1.

In view of the foregoing the Board judges that the subject-matter of the set of claims of the main request is novel as required by Article 54 EPC.



**Order**

**For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The case is remitted to the first instance for further prosecution.

The Registrar:

The Chairman:

A. Townend

P. Lançon