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**Datasheet for the decision  
of 1 March 2012**

**Case Number:** T 2256/08 - 3.3.02

**Application Number:** 99917591.2

**Publication Number:** 1071428

**IPC:** A61K 31/565

**Language of the proceedings:** EN

**Title of invention:**

Folic acid-containing pharmaceutical compositions, and related methods and delivery systems

**Applicants:**

Ortho-McNeil Pharmaceutical, Inc.  
The Government of the United States represented by the  
Secretary of the Department of Health and Human Services

**Headword:**

Folic acid containing pharmaceutical compositions/ORTHO-McNEIL

**Relevant legal provisions:**

EPC Art. 84  
RPBA Art. 13

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

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**Keyword:**

"Main request - clarity (no): wording of the claim inconsistent; subject-matter not defined in a complete and unambiguous manner of the claim"

**Decisions cited:**

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**Catchword:**

-



Case Number: T 2256/08 - 3.3.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.02  
of 1 March 2012

**Appellants:**  
(Applicants)

Ortho-McNeil Pharmaceutical, Inc.  
U.S. Route No.202  
Raritan  
NJ 08869-0602 (US)

The Government of the United States  
represented by  
the Secretary of the Department of Health and  
Human Services  
The Centers for Disease Control and Prevention  
1600 Clifton Road N.E.  
Atlanta, GA 30333 (US)

**Representative:**

Mercer, Christopher Paul  
Carpmaels & Ransford  
One Southampton Row  
London WC1B 5HA (GB)

**Decision under appeal:**

**Decision of the Examining Division of the  
European Patent Office posted 9 May 2008  
refusing European patent application  
No. 99917591.2 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman:** U. Oswald  
**Members:** D. Boulois  
L. Bühler

## Summary of Facts and Submissions

- I. European patent application No. 99 917 591.2 was refused by a decision of the examining division pronounced on 21 April 2008 on the grounds of non-compliance with Articles 123(2) and 56 EPC.
- II. The decision was based on the main request and auxiliary requests 1-3 filed during the oral proceedings of 21 April 2008.

The sole claim of the main request read:

"1. Use of (a) an oral contraceptive for preventing pregnancy in a subject and (b) folic acid in the manufacture of a medicament for reducing the risk of neural tube defects in a foetus developing in said subject following discontinuation of use of the medicament and/or following a positive pregnancy test result".

The sole claim of auxiliary request 1 read:

"1. Use of a pharmaceutical composition comprising (a) an oral contraceptive for preventing pregnancy in a subject and (b) folic acid in the manufacture of a medicament for reducing the risk of neural tube defects in a foetus developing in said subject following becoming pregnant".

The sole claim of auxiliary request 2 read:

"1. Use of (a) an oral contraceptive for preventing pregnancy in a subject and (b) folic acid in the manufacture of a medicament for reducing the risk of neural tube defects in a foetus developing in said subject within 6 months following discontinuation of

use of the medicament and/or following a positive pregnancy test result".

Claims 1 and 2 of auxiliary request 3 read:

"1. Use of (a) an oral contraceptive for preventing pregnancy in a subject and (b) folic acid in the manufacture of a medicament for treating or preventing cervical dysplasia, cervical carcinoma or a cardiovascular disorder.

"2. Use (a) an oral contraceptive for preventing pregnancy in a subject and (b) folic acid in the manufacture of a medicament for preventing neural tube defects in a foetus developing in said subject following becoming pregnant after discontinuation of use of the medicament".

III. The documents cited during the examination proceedings included the following:

- (3) WO88/04927 A
- (4) Rhode et al: "Effect of Orange Juice, Folic Acid, and Contraceptives on Serum Folate in Women taking a Folate-Restricted Diet", J. Am. Coll. Nutr., vol. 2, No 3, 1983, pages 221-230, XP002114784
- (5) Butterworth et al: "Improvement in Cervical Dysplasia Associated with Folic Acid Therapy in Users of Oral Contraceptives", Am. J. Clin. Nutr., vol 35, No 1, 1982, Pages 73-82, XP002114785
- (8) "Recommendations for the Use of Folic Acid to reduce the Number of Cases of Spina Bifida and other Neural Tube Defects". Morbidity and Mortality Weekly Report (MMWR), vol. 41 (RR-14), 1992, pages 1-7.

IV. In the decision under appeal, the examining division held that the main request did not meet the requirements of Article 123(2) EPC, auxiliary request 1 did not meet the requirements of Article 56 EPC, auxiliary request 2 did not meet the requirements of Article 123(2) EPC and auxiliary request 3 did not meet the requirements of Article 123(2) and 54 EPC.

The examining division considered that the feature "*developing in said subject following discontinuation of use of the medicament and/or following a positive pregnancy test result*" and the absence of the expression "*in the form of a composition*" in claim 1 of the main request constituted an infringement of Article 123(2) EPC.

In connection with the finding of lack of inventive step of the subject-matter of claim 1 of auxiliary request 1, document (8) was seen to represent the closest prior art. The problem to be solved by the present application was defined as finding the means to reduce the risk of neural tube defects in a foetus developing in a subject becoming pregnant despite taking contraceptives or following discontinuation of use of the oral contraceptive.

The solution was found to be obvious in view of document (8), as this document taught the folic acid supplementation to women capable of becoming pregnant. The oral contraceptives were known from documents (3)-(5) to deplete the stock of folic acid.

The examining division found that auxiliary request 2 did not meet the requirements of Article 123(2) EPC, since no basis was found for the amendment "*within 6*

months" in claim 1 in addition to the objections already raised for the main request.

The examining division considered that auxiliary request 3 did not meet the requirements of Article 123(2) EPC for the same reasons as were given for the main request and since the term "*preventing*" in claim 2 had no basis in the original application. Furthermore, the subject-matter of claim 1 of auxiliary request 3 did not meet the requirements of Article 54 EPC since it was not novel over document (5).

- V. The appellant (applicant) lodged an appeal against that decision.
  
- VI. With a letter dated 19 September 2008, the appellant filed a new main request and auxiliary requests 1 and 2, all replacing the previous requests, and arguments regarding Article 123(2) and 56 EPC.
  
- VII. With a letter dated 1 February 2012, the appellant filed a new main request and auxiliary request 1 to replace the requests on file.
  
- VIII. Oral proceedings before the board of appeal took place on 1 March 2012.  
During oral proceedings, the main request was objected to by the board under Article 123(2) EPC. The appellant withdrew the main request of 1 February 2012 and submitted a new main request in which the term "*foetus*" had been replaced by the term "*embryo*" and withdrew auxiliary request 1 filed with the letter of 1 February 2012.

The sole claim of the main request read as follows:

"1. A pharmaceutical composition comprising (a) an oral contraceptive for preventing pregnancy in a subject and (b) folic acid in the manufacture of a medicament for use in a method of reducing the risk of neural tube defects in an embryo developing in said subject following becoming pregnant".

IX. The appellant's arguments can be summarised as follows:

The invention lies in the use of a composition comprising an oral contraceptive and folic acid in the prophylaxis of neural tube defects of the embryo; there is no inconsistency in the treatment of a woman under contraception to benefit an embryo which may lead to a birth. The composition is to be taken regularly, on an everyday basis, by women in order to increase their store of folic acid. It is a chronic prophylactic treatment.

The person who receives the treatment is not the person who benefits from the treatment, since the embryo does not yet exist.

Oral contraceptives are not 100% effective, and this composition may be the only possibility to reduce the incidence of neural tube defects.

Moreover, when a woman decides to stop contraception, it will take some time to replete the body stock of folic acid and the period after stopping contraception is a period of a low folic acid level. This problem is remedied by the present invention.

The treatment can be seen as prophylactic, in case of accidental discontinuation of contraception, of an accidental unwanted pregnancy of a woman taking an oral contraceptive, and for a woman deciding to become pregnant and therefore stopping contraception.

- X. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request received during oral proceedings of 1 March 2012.

### **Reasons for the decision**

1. The appeal is admissible.
2. Admission of the main request (Article 13 RPBA)

The main request was filed during oral proceedings and is a direct response to the objection under Article 123(2) EPC raised by the board against the former main request. Moreover, the amendments are of a clear and simple nature. Consequently, the main request is admissible.

3. Main request - Article 84 EPC
  - 3.1 Article 84 EPC requires that the claims shall define the matter for which protection is sought. They must be clear and concise and supported by the description.
  - 3.2 Claim 1 of the main request is in the form of a purpose-related product claim and seeks protection for a composition for use in a medical treatment. In particular, claim 1 concerns a composition comprising an oral contraceptive and folic acid to be administered to a subject, and the medical use is a method of reducing the risk of neural tube defects in an embryo developing in said subject following becoming pregnant.



The subject of claim 1 therefore concerns the **concomitant and continuous** administration of an oral contraceptive and folic acid **to any subject or group of subjects** to reduce the risk of neural tube defects in the embryo.

The subject-matter of claim 1 is seen as consistent only in particular situations. Such cases comprise an accidental discontinuation of the oral contraception or an unintentional pregnancy under oral contraception. In both cases the woman would temporarily continue to take the composition of folic acid together with the contraceptive, as long as it is not known whether pregnancy has have occurred.

The subject-matter of claim 1 is however not restricted to this particular situation or group of subjects.

On the other hand, the subject-matter of claim 1 is inconsistent with a situation concerning a group of women wishing to become pregnant and discontinuing oral contraception for that purpose. Such a group of women cannot be concerned by the treatment as claimed in claim 1, which relates exclusively to subjects taking concomitantly and continuously an oral contraceptive and folic acid.

Thus, claim 1 of the main request does not define the invention in a complete manner and is inconsistent. Consequently, the claim does not meet the requirements of Article 84 EPC.

- 3.3 In the applicant's view, the subject-matter of claim 1 must be seen as the chronic administration of a prophylactic composition. The prophylaxis benefits a

person different from the person receiving the treatment, since at the time of the administration, the embryo is not present. This situation does not present any contradiction; the prophylaxis stops when the embryo is formed.

- 3.4 The board could however not follow this opinion. The subject-matter of claim 1 has to be analysed in its whole scope and exact wording. It is sufficient that one single alternative encompassed by the subject-matter of the claim presents a contradiction or inconsistency to render the said claim unclear. Claim 1 relates to the chronic administration of a prophylactic composition comprising *inter alia* an oral contraceptive. There is no further restriction in claim 1 regarding a specific group of subject or a subsequent administration of the composition without the contraceptive. The presence of an oral contraceptive in the composition has the consequence that the treatment should only concern a specific group of subject, namely subjects not wishing to get pregnant. However, the claim does not make any distinction regarding the group of patients to be treated, **and therefore covers all possible situations and groups of subjects.** Oral contraception is however inconsistent with the treatment of some groups of subjects. Such a group is for instance discussed in the description (see description, page 3, lines 26-30); this particular group of subjects "*become pregnant within three to six months following discontinuation of oral contraception*". The further administration of a

composition comprising *inter alia* an oral contraceptive to these subjects is inconsistent and contra-indicated.

Consequently, the subject-matter of claim 1 presents an inherent contradiction.

3.5 The main request does not meet the requirements of Article 84 EPC.

## **Order**

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

The appeal is dismissed.

The Registrar:

The Chairman:

N. Maslin

U. Oswald