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**Datasheet for the decision
of 22 December 2010**

Case Number: T 2023/07 - 3.3.02

Application Number: 98953609.9

Publication Number: 1024803

IPC: A61K 31/35

Language of the proceedings: EN

Title of invention:

Flavonoids for cystic fibrosis therapy

Applicant:

Children's Hospital & Research Center at Oakland

Headword:

Flavonoids for cystic fibrosis therapy/CHILDREN'S HOSPITAL &
RESEARCH CENTER AT OAKLAND

Relevant legal provisions:

EPC Art. 123(2), 83, 111

Relevant legal provisions (EPC 1973):

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Keyword:

"Main request - allowability of amendments, sufficiency -
(yes) "

"Remittal - (yes): undecided issues"

Decisions cited:

-

Catchword:

-



Case Number: T 2023/07 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 22 December 2010

Appellant: Children's Hospital & Research Center at
Oakland
747 52nd Street
Oakland, CA 94609-1809 (US)

Representative: Walker, Ross Thomson
Forrester & Boehmert
Pettenkoferstraße 20-22
D-80336 München (DE)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 3 May 2007
refusing European patent application
No. 98953609.9 pursuant to Article 97(1) EPC
1973.

Composition of the Board:

Chairman: U. Oswald
Members: A. Lindner
J. Van Moer

Summary of Facts and Submissions

I. European patent application No. 98 953 609.9 was refused by a decision of the examining division posted on 3 May 2007 on the basis of Article 97(1) EPC 1973 on the grounds that the subject-matter of the main request (i.e. claims 1-19 filed with letter dated 9 June 2005) lacked novelty and an inventive step. Auxiliary requests 1 to 3, all filed with letter of 21 July 2005 were not admitted into the proceedings pursuant to Rule 86(3) EPC 1973.

II. The independent claims of the main request read as follows:

"1. A method for enhancing chloride transport in epithelial cells in vitro comprising contacting epithelial cells with a compound selected from the group consisting of flavones and isoflavones, preferably, daidzein or prunetin, wherein the compound is capable of stimulating chloride transport and wherein the compound is not genistein.

3. The use of a composition comprising one or more compounds selected from the group consisting of flavones and isoflavones for the manufacture of a medicament for use in treating cystic fibrosis in a mammal, wherein the compound is not genistein.

17. A pharmaceutical composition for treatment of cystic fibrosis comprising:

(a) one or more flavones or isoflavones capable of stimulating chloride secretion, wherein said isoflavone is not genistein;

- (b) one or more of:
 - (i) a compound that increases expression of CFTR
in an epithelial cell; and/or
 - (ii) a chemical chaperone that increases
trafficking of a CFTR to a plasma membrane in
an epithelial cell; and
- (c) a physiologically acceptable carrier."

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

- (1) T.-C. Huang, et al., Am. J. Physiol. (1997),
vol. 273, C988-C998
- (11) B. Illek, et al., Am. J. Physiol. (1996),
vol. 270, C265-C275

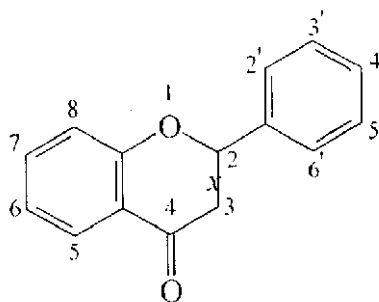
IV. The arguments in the first-instance decision may be summarised as follows:

The subject-matter of claim 1 was not novel over document (11), wherein daidzein was tested for CFTR stimulation. As regards inventive step, document (11) was considered to constitute the closest prior art. The problem to solved with regard to document (11) was defined as the provision of further flavones or isoflavones for the treatment of cystic fibrosis except for genestein. In view of the fact that there were no data demonstrating a beneficial effect for the flavones and isoflavones of claim 1, the subject-matter claimed therein lacked an inventive step.

- V. The appellant (applicant) lodged an appeal against this decision.
- VI. With a letter of 12 May 2010, the appellant was invited to oral proceedings.
- VII. In a communication dated 15 September 2010, the board raised objections under Article 83 EPC in connection with daidzein. These objections were reiterated by the rapporteur in a telephone conversation with Mr. Walker on 3 November 2010.
- VIII. With a letter of 11 November 2010, the appellant filed a new main request. The independent claims read as follows:

"1. The use of a composition comprising one or more compounds selected from the group consisting of flavones for the manufacture of a medicament for use in treating cystic fibrosis in a mammal, wherein the compound is:

(a) a polyphenolic compound having the general formula;



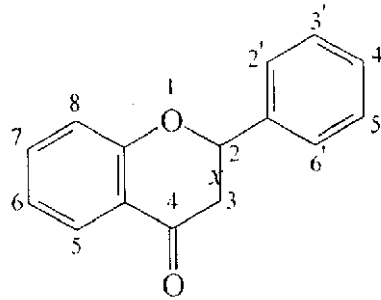
wherein carbon atoms at positions 2, 3, 5, 6, 7, 8, 2', 3', 4', 5' and 6' are bonded to a moiety independently selecting from the group consisting of hydrogen atoms,

hydroxyl groups and methoxyl groups, and wherein X is a double bond: or

(b) a glycoside derivative of any of the foregoing polyphenolic compounds; wherein the compound is not genistein.

12. A pharmaceutical composition for treatment of cystic fibrosis. comprising:

(a) one or more flavones capable of stimulating chloride secretion, wherein the flavone comprises a polyphenolic compound having the general formula:



wherein carbon atoms at positions 2, 3, 5, 6, 7, 8, 2', 3', 4', 5' and 6' are bonded to a moiety independently selected from the group consisting of hydrogen atoms, hydroxyl groups and methoxyl groups, and wherein X is a double bond; or a glycoside derivative of any of the foregoing polyphenolic compounds;

(b) one or more of:

- (i) a compound that increases expression of a CFTR in an epithelial cell; and/or
- (ii) a chemical chaperone that increases trafficking of a CFTR to a plasma membrane in an epithelial cell; and

(c) a physiologically acceptable carrier."

- IX. In a further telephone conversation on 12 November 2010, the rapporteur informed the applicant that in the light of the appellant's new main request, the board intended to cancel the oral proceedings and to remit the case to the examining division for further prosecution, to which the appellant gave his consent.
- X. The oral proceedings were cancelled with a fax dated 12 November 2010.
- XI. The appellant requested in writing that the decision under appeal be set aside and that the case be remitted to the examining division for further prosecution of the main request filed with letter of 11 November 2010.

Reasons for the decision

1. The appeal is admissible.
2. *Main request:*
 - 2.1 Amendments:

The subject-matter of claim 1 is based on claims 30 and 31 of the original application, which were reformulated as Swiss type claims and wherein the active agents were restricted to flavones. The subject-matter of claim 12 is based on claim 51 and the passage on page 10, line 20 - page 11, line 14 of the original application. The requirements of Article 123(2) EPC are therefore met.

2.2 Sufficiency of disclosure:

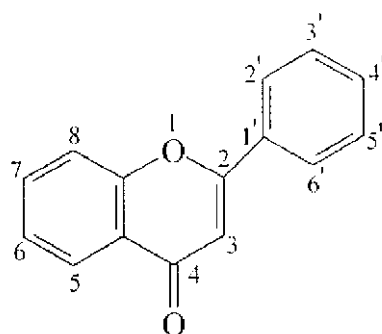
In view the fact that the claimed subject-matter is now limited to flavones, the objections concerning insufficiency of disclosure in connection with daidzein raised in the board's communication of 15 September 2010 do no longer apply. As a consequence, the requirements of Article 83 EPC are met.

3. *Remittal to the department of first instance*

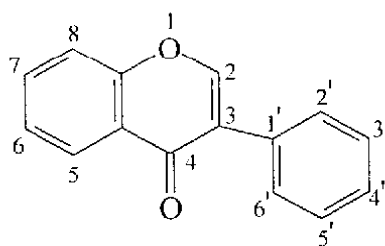
3.1 Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party may be given the opportunity of two readings of the important elements of the case. The essential function of an appeal is to consider whether the decision issued by the first-instance department is correct. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

In particular, remittal is considered by the boards in cases where a first-instance department issues a decision against a party based upon certain issues only which are decisive for the case, and leaves other essential issues outstanding. If, following appeal proceedings, the appeal on the particular issues is allowed, the case is normally remitted to the first-instance department for consideration of the undecided issues (Article 111 EPC).

3.2 The observations made above apply fully to the present case. The refusal on the grounds of lack of novelty and lack of inventive step was only based on documents (1) and (11), which do no longer appear to be pertinent with regard to the amendments made in the present main request: Both genestein and daidzein belong to the class of isoflavones.



Flavone



Isoflavone

As can be seen from the above formulae, flavones, where the carbonyl group in position 4 is conjugated to the aromatic π -system of the phenyl ring via the double bond in position 2-3, are structurally different from isoflavones, where this is not the case. It appears therefore that documents (1) and (11) are no longer pertinent for novelty and inventive step. Therefore, it

has to be examined whether the grant of the patent is prejudiced by any of the other documents on file. Moreover, the requirements of Article 84 EPC should also receive attention. Thus, it appears that the disclaimer in present claim 1 is no longer necessary in the light of the limitation to flavones.

3.3 Therefore, in view of the above considerations, the board has reached the conclusion that in the circumstances of the present case, it is necessary to remit the case to the first instance for further prosecution.

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

D. Meyfarth

U. Oswald