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**D E C I S I O N**  
**of 20 July 2004**

**Case Number:** W 0020/03 - 3.3.1

**Application Number:** PCT/PL 02/00029

**Publication Number:** WO 2002/081491

**IPC:** C07H 15/26

**Language of the proceedings:** EN

**Title of invention:**

New genistein derivatives and pharmaceutical preparations  
containing them

**Applicant:**

INSTYTUT FARMACEUTYCZNY

**Opponent:**

-

**Headword:**

Genistein/Pharmaceutical Institute

**Relevant legal provisions:**

PCT Art. 17(3) (a)

PCT R. 13, 40

PCT Administrative Instructions, Annex B, Part 1, (f)

**Keyword:**

"Obligation under Rule 40.1 PCT to specify reasons not met in  
view of PCT guidelines"

**Decisions cited:**

G 0001/89, W 0004/93, W 0011/93, W 0003/94

**Catchword:**

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Case Number: W 0020/03 - 3.3.1

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.1  
of 20 July 2004

**Applicant:** INSTYTUT FARMACEUTYCZNY  
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**Representative:** -

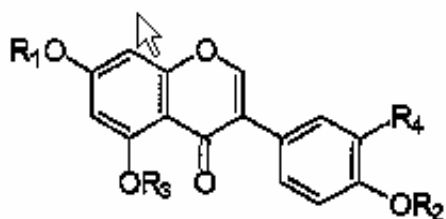
**Decision under appeal:** Protest according to Rule 40.2(c) of the Patent  
Cooperation Treaty made by the applicants  
against the invitation (payment of additional  
fees) of the European Patent Office  
(International Searching Authority) dated  
12 July 2002 .

**Composition of the Board:**

**Chairman:** A. Nuss  
**Members:** R. Freimuth  
B. Günzel

## Summary of Facts and Submissions

- I. Following the filing of international application No. PCT/PL 02/00029 the EPO, acting as ISA, on 12 July 2002 issued an invitation to pay within 30 days 10 additional search fees (Article 17(3)(a) and Rule 40.1 PCT).
- II. The said international application contained 7 claims. Independent claim 1 was directed to genistein derivatives of formula I



wherein

R<sub>1</sub> and R<sub>2</sub> are the same or different and independently represent:

hydrogen atom, alkyl, aryl, alkyloaryl, alkylcarbonyl, arylcarbonyl, while each of the above mentioned groups may be substituted in a chain or ring by amino, nitro or nitrile groups,

R<sub>5</sub>(R<sub>6</sub>)R<sub>7</sub>-Si-group wherein R<sub>5</sub>, R<sub>6</sub> and R<sub>7</sub> are the same or different and denote C<sub>1-6</sub>alkyl or aryl,

mono-, di- or oligosaccharide group while at least one hydroxyl group of saccharide group may be substituted by the same or different acyl, alkyl, acyloxyalkyl or aryl groups;

R<sub>3</sub> represents hydrogen atom or -COCH<sub>3</sub> group; and

R<sub>4</sub> represents hydrogen atom, -SO<sub>3</sub>H, SO<sub>3</sub><sup>-</sup> or -NH<sub>2</sub> or -NO<sub>2</sub> group; and their pharmaceutically acceptable salts.

Independent claim 7 was directed to a pharmaceutical preparation containing a genistein derivative of that formula I. Claims 2 to 6 were dependent on claim 1 and referred to preferred embodiments within the ambit of that claim.

III. The ISA stated in the invitation to pay additional fees (IPAF) that the international application related to 11 groups of inventions. Each group thereof was defined as referring to genistein derivatives of formula I, wherein the substituent  $R_1$  or the substituents  $R_1$  and  $R_2$  had a particular meaning selected from the list given in claim 1, and to pharmaceutical compositions containing them.

The ISA held that the problem underlying the present application was the provision of further antitumor genistein derivatives. That problem was solved by using the substituted genistein skeleton of formula I. However, the documents

(1) WO-A-98/48790 and

(2) FR-A-2 781 154

disclosed the individual compound genistein falling within the scope of the present application. This compound was taught to be useful in the treatment of cancer and to be a cytotoxic agent for treating tumors. Genistein disclosed in documents (1) and (2), thus, solved the problem in an identical manner to the present application. In the light of those documents the solution proposed in the present application to the

problem of providing further antitumor compounds was known from the prior art. Therefore the use of these genistein derivatives as antitumor agents could not be regarded as the special technical feature linking together the separate inventions disclosed in the present application. In the absence of other features linking together the separate inventions, there was a lack of unity.

- IV. On 12 August 2002 the Applicant paid 10 additional search fees under protest (Rule 40.2(c) PCT). In support of the protest the Applicant submitted that the application should be considered as complying with the requirement of unity since the independent claims define a group of chemical compounds being of a similar nature, i.e. alternatives, and since a technical relationship between the alternatives did exist. The 11 inventions identified by the ISA were alternatives which all had a common activity and a significant common structural element, namely the 3-phenyl-chromen-4-one ring system. Since the claimed compounds possessed the same antiproliferative and antitumor activity, the second condition for the unity of invention was satisfied. The Instructions under the PCT concerning unity of invention indicated, in case a claim was not delimited from the prior art, that an objection of lack of unity could only be raised after a particular assessment.

The Applicant requested that the additional search fees be refunded.

- V. On 27 January 2003 the ISA's Review Panel informed the Applicant that, after having performed the prior review

pursuant to Rule 40.2(e) PCT, it found the IPAF completely justified and invited the Applicant to pay the protest fee within one month. It confirmed the reasoning given in the IPAF and stated that the lack of unity lay in the finding that the individual compound genistein as well as its use as antitumor agent was known in the art. Therefore neither the group of compounds identified by the applicant was novel nor the 3-phenyl-chromen-4-one ring system which, thus, was not the distinguishing structure. "In this case the reconsideration of §f(v) lead[s] to the conclusion that there [was] no special technical features in the sense of Rule 13.1 PCT that technically link[ed] all compounds under a single general inventive concept in the sense of Rule 13.2 PCT." For this reason, non-unity existed within the subject-matter claimed.

VI. On 24 February 2003 the Applicant paid the protest fee.

### **Reasons for the Decision**

1. The protest is admissible.
  
2. According to Rule 13.1 PCT, the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. If the ISA considers that the claims lack this unity, it is empowered to invite the Applicant to pay additional fees pursuant to Article 17(3) (a) PCT.

Lack of unity of invention may be directly evident *a priori*, i.e. before the examination of the merits of

- the claims in comparison with the state of the art revealed by the search. Alternatively, the ISA is also empowered to raise that objection *a posteriori*, i.e. after having taken into account the state of the art revealed by the search (see decision G 1/89, OJ EPO 1991, 155). In the present case, the ISA raised the objection of non-unity based on the prior art documents (1) and (2) and was thus made *a posteriori*.
3. Rule 40.1 PCT stipulates that the invitation under Article 17(3)(a) PCT to pay additional fees must specify the reasons for which the international application is not considered as complying with the requirement of unity. Thus, the invitation needs to comprise a conclusive reasoning substantiating not only the finding of lack of novelty or inventive step of the single invention defined in the independent claim, but substantiating also the finding for lack of unity between the newly defined alternative groups of inventions (see decision W 3/94, OJ EPO 1995, 775, point 6 of the reasons).
  4. In the present case, the ISA divided the subject-matter of claim 1 defined in the form of a *Markush*-formula (see point II *supra*) into 11 separate groups of inventions due to a novelty destroying disclosure of the individual compound genistein in documents (1) and (2).
  5. In the invitation to pay the additional fees, the sole reason given for the ISA's non-unity objection was that the claimed compounds neither shared a new structural element in view of documents (1) and (2) nor showed a

new activity in the light of what was described in that prior art.

6. Thus, the issue arises whether or not the ISA thereby satisfied its obligation to substantiate its findings.

Pursuant to Article 2 of the Amended Agreement between the EPO and the International Bureau of WIPO (OJ EPO 2001, 601) the international search shall be carried out in accordance with the Treaty, its Regulations and the Administrative Instructions; when carrying out the international search under the PCT, the International Search Guidelines shall guide it. Chapter VII-1 of those Search Guidelines stipulates that when assessing unity of invention in accordance with the provisions laid down in Rule 13.1 to 13.4 PCT, *inter alia* Annex B of the Administrative Instructions under the PCT are to be observed. It follows therefrom that in the assessment of unity the Administrative Instructions are binding not only for the ISA but also for the Board acting as the "three-member board" according to Rule 40.2(c) PCT (see decisions G 1/89, *loc cit.*; W 3/94, *loc cit.*, point 10 of the reasons).

7. Part 1 (f) of Annex B of the Administrative Instructions specifies certain criteria for deciding on the unity of *Markush* claims. In respect of the alternatives comprised in such claims, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2 PCT is considered to be met when the alternatives are of a similar nature.



According to Part 1 (f) (i) of Annex B of the Administrative Instructions alternatives are to be regarded as "of a similar nature" where

- (A) all alternatives have a common property or activity, and
- (B) (2) in cases where the common structure cannot be the unifying criterion, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

A "recognized class of chemical compounds" in the sense of (B) (2) *supra* is defined in section (f) (iii) of that Part 1 and means that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention.

- 8. The Administrative Instructions indicate in Annex B, Part 1, section (f) (v) that in case one *Markush* alternative is not novel over the prior art, the question of unity of invention should be reconsidered, although "reconsideration does not necessarily imply that an objection of lack of unity shall be raised". Thus, an IPAF only gives "the reasons" in the sense of Rule 40.1 PCT if it specifies why the case at issue does not comply with the criterion indicated in Annex B, Part 1, section (f) (i) (B) (2).
- 9. In the present case, the justification given in the IPAF specifies that the 11 groups of inventions as defined therein belong to a known and recognized class of compounds with antitumor activity, which is the

genistein skeleton or, in chemical terms, the 3-phenyl-chromen-4-one ring system. The ISA's findings appear to indicate, however, that this class of compounds complies with the criteria laid down in Annex B, Part 1, section (f)(i), paragraphs (A) and (B)(2) of the Administrative Instructions. Therefore, the ISA's justification in the IPAF seems to point rather to a group of inventions to be regarded as having unity within the meaning of the Administrative Instructions, Annex B. Thus, the IPAF falls short of substantiating the finding of lack of unity between the newly defined alternative groups of inventions in respect of the relevant PCT Administrative Instructions.

10. However, an invitation which is based on such a deficient justification does not "specify the reasons" in the sense of Rule 40.1 PCT. For that reason, the IPAF does not meet the requirements of that Rule and, therefore, does not provide a proper basis for retaining the additional fees paid under protest.
  
11. The Board notes that in the Notification regarding the Review of Justification for the IPAF the ISA's Review Panel referred for the first time to the term "reconsideration" addressed in Annex B, Part 1, section (f)(v) of the Administrative Instructions (see point V *supra*), without, however, additionally substantiating the deficient justification given in the IPAF. Thus, the Notification regarding the Review does not overcome the deficiencies in the justification of the IPAF and it could not do so since fresh reasons given by the Review Panel were to be disqualified anyway (see e.g. W 4/93, OJ EPO 1994, 993, point 2.2 of

the reasons; W 11/93, point 3.3 of the reasons, not published in OJ EPO).

**Order**

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

The reimbursement of the additional search fees and the protest fee paid is ordered.

The Registrar:

The Chairman:

N. Maslin

A. Nuss