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Beschwerdekammem

Boards of Appeal

Chambres de recours

Case Number: W 0008/99 - 3.3.1

International Application No. PCT/US 98/08471

DECISION of the Technical Board of Appeal 3.3.1 of 28 September 1999

Hoechst Marion Roussel, Inc. 2110 East Galbraith Road P.O. Box 156300 Cincinnati Ohio 45215-6300 (US)

Representative:

Gupta, Balaram 2110 East Galbraith Road P.O. Box 156300 Cincinnati Ohio 45215-6300 (US)

Subject of the Decision:

Protest according to Rule 68.2(c) of the Patent Cooperation Treaty made by the applicants against the invitation (payment of one additional fee) of the European Patent Office (International Preliminary Examining Authority) dated 29 December 1998.

Composition of the Board:

Chairman:

A. Nuss

Members:

P. Bracke R. Teschemacher

## Summary of Facts and Submissions

- I. International patent application PCT/US 98/08471 was filed on 27 April 1998 with thirteen claims of which the independent claims read:
  - "1. A process for preparing a compound of the formula:

wherein R is  $C_1$ - $C_{10}$  alkyl, phenyl or substituted phenyl, comprising treating a compound of the formula:

with bis(tributyltin) oxide in an organic solvent selected from the group consisting of o-xylene, m-xylene, p-xylene and mixed xylenes; and subsequently treating the reaction mixture with a compound of the formula:

wherein X is halogen and R is defined as above."

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### "2. A process for preparing a compound of the formula:

wherein R is C<sub>1</sub>-C<sub>10</sub> alkyl, phenyl or substituted phenyl; and Y is an acid selected from the group consisting of hydrogen bromide, hydrogen chloride, sulfuric acid, phosphoric acid, nitric acid, formic acid, acetic acid, propionic acid, succinic acid, glycolic acid, lactic acid, malic acid, tartaric acid, citric acid, ascorbic acid, α-ketoglutaric acid, glutamic acid, aspartic acid, maleic acid, hydroxymaleic acid, pyruvic acid, phenylacetic acid, benzoic acid, p-aminobenzoic acid anthranilic acid, p-hydroxybenzoic acid, salicyclic acid, hydroxyethanesulfonic acid, ethylenesulfonic acid, halobenzenesulfonic acid, toluenesulfonic acid naphthalenesulfonic acid, methanesulfonic acid and sulfanilic acid, comprising;

#### (a) treating a compound of the formula

with bis(tributyltin) oxide in an organic solvent selected from the group consisting of o-xylene, m-xylene, p-xylene and mixed xylenes;

and subsequently treating the reaction mixture with a compound of the formula:

wherein X is halogen and R is defined as above; and

- (b) subsequently treating the reaction mixture with a suitable organic solvent and an acid of formula Y defined above."
- "11. A process for purifying a compound of the formula:

wherein R is C<sub>1</sub>-C<sub>10</sub> alkyl, phenyl or substituted phenyl; and Y is an acid selected from the group consisting of hydrogen bromide, hydrogen chloride, sulfuric acid, phosphoric acid, nitric acid, formic acid, acetic acid, propionic acid, succinic acid, glycolic acid, lactic acid, malic acid, tartaric acid, citric acid, ascorbic acid, α-ketoglutaric acid, glutamic acid, aspartic acid, maleic acid, hydroxymaleic acid, pyruvic acid, phenylacetic acid, benzoic acid, p-aminobenzoic acid, anthranilic acid, p-hydroxybenzoic acid, salicyclic acid, hydroxyethanesulfonic acid, ethylenesulfonic acid, halobenzenesulfonic acid, toluenesulfonic acid, naphthalenesulfonic acid, methanesulfonic acid and sulfanilic acid, comprising;

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- (a) combining above said compound with about a 95/5 v/v solution of ethanol and water to provide about a 13% by weight solution of said compound;
- (b) heating the solution at reflux with agitation;
- (c) cooling the solution to about 54°C;
- (d) seeding the solution with said compound to produce a crystal slurry;
- (e) heating the crystal slurry at about 64°C until the crystal slurry is reduced by about 70% to about 80%;
- (f) maintaining the temperature of the crystal slurry at about 64°C for about 2 hours;
- (g) initiating a suitable cooling profile to provide a final temperature of the crystal slurry of less than about 0°C;
- (h) collecting the purified compound."

Claims 3 to 10 were dependent on Claim 1 or 2 and Claims 12 and 13 were dependent on Claim 11.

On 29 December 1998 the European Patent Office (EPO) acting as an International Preliminary Examining Authority (IPEA), informed the applicant that the application did not comply with the requirement of unity of invention and invited him to restrict the claims or to pay one additional examination fee pursuant to Article 34(3)(a) and Rule 68.2 PCT within a period of one month.

In an annex to this invitation the IPEA submitted that the application related to two inventions, namely:

group (i): Claims 1 to 10 relating to a process for preparing 6-monoesters of castanospermine or an acid addition salt thereof and

group (ii): Claims 11 to 13 relating to a process for purifying an acid addition salt of 6-monoesters of castanospermine.

Since the common concept linking the two groups of invention could only lie in the acid addition salts of 6-monoesters of castanospermine and since these compounds were known from inter alia document (1), Tetrahedron, vol. 50 (1994), No. 7, pages 2131-2160, the IPEA was of the opinion that the two inventions were not linked by a single inventive concept.

- With letter received on 27 January 1999, the applicant paid one additional fee under protest pursuant to Rule 68.3(c) PCT and in his reasoned statement he submitted that both inventions were closely related having a common goal, namely, to provide a novel process for the preparation of purified acid salts of 6-monoesters of castanospermine.
- On 11 February 1999, the IPEA issued a communication informing the applicant that after a prior review of the justification for the invitation to pay an additional fee, the requirement of payment thereof was upheld. The applicant was thus invited under Rule 68.3(e) PCT to pay the protest fee.
- V. The protest fee was paid in due time.

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#### Reasons for the Decision

- 1. According to Article 155(3) EPC the Boards of Appeal of the EPO are responsible for deciding on a protest made by an applicant against an additional fee charged by the EPO under the provisions of Article 34(3)(a) PCT. The Board is thus competent for examining the present protest.
- 2. The protest is admissible
- 3. From the separate sheet to the invitation for paying the protest fee it follows that the review panel, which decided on the justification for inviting to pay an additional fee, was composed of three members as prescribed by the President of the EPO (OJ EPO 1992, 547) and was thus competent for inviting to pay a protest fee.
- 4. According to Rule 13.1 and 13.2 PCT the requirement of unity of invention may only be fulfilled if a group of inventions is so linked as to form a single general inventive concept, ie if there is a technical relationship among the inventions involving one or more of the same or corresponding technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.
- 5. It follows from the application in suit that a process for preparing 6-monoesters of castanospermine by treating castanospermine with bis(tributyltin) oxide in toluene and, subsequently, with an acid chloride was known from document (1) (see the application as filed, page 2, line 25 to page 3, line 7). Furthermore, it follows from the application that the technical problem underlying the invention was the fact that the time

required to drive the formation of the tributyltin ether to completion through removal of water increases as the size of the reaction is increased and that, according to the present invention, it has been found that by replacing toluene with xylene as the solvent in the process described in document (1), the time required to drive the reaction to completion by removal of water is substantially decreased (page 3, lines 8 to 13, of the application as filed).

Consequently, the technical feature defining a contribution over the prior art of group (i) is the use of a xylene instead of toluene in a process of preparing castanospermine or an acid addition salt thereof, thus avoiding the disadvantages of the process known from document (1).

- 6. This technical feature is not present in the invention according to group (ii): since the invention concerns a specific process of purifying acid addition salts of castanospermine, the technical feature defining a contribution over the prior art is the combination of steps (a) to (h) as defined in Claim 11 in order to purify acid addition salts of 6-monoesters of castanospermine, independent thereof whether this acid addition salt has been obtained according to a process as defined in Claims 1 to 10.
- 7. Since in the inventions according to group (i) and group (ii) completely different technical features define a completely different contribution over the prior art, there is no technical relationship involving the same technical feature among both groups of inventions and, consequently, the requirement of unity of invention according to Rule 13.1 and 2 PCT is not fulfilled.

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8. The Applicant was of the opinion that both inventions had a common goal, namely, to provide a process for the preparation of purified acid salts of 6-monoesters of castanospermine.

However, the Board cannot follow this reasoning, since the group (i) inventions are not related to a process of preparing purified castanospermine or acid addition salts thereof, but to a process of preparing any castanospermine or acid addition salt thereof, independently of whether it is obtained in a pure form or whether an additional purification step is conducted.

That the purification step is not restricted to be applied to products obtained according to Claims 1 to 10 and that any purification step may be used is clearly confirmed by the teaching on page 8, lines 20 to 22, of the application as filed, where it is said that the acid addition salt of castanospermine resulting from the preparation process may be isolated and purified by techniques well known by one of ordinary skill in the art, such as crystallisation.

9. For the foregoing reasons, the Board comes to the conclusion that the inventions according to group (i) and group (ii) do not form a single general inventive concept and, consequently, that the invitation made under Article 34(3)(a) and Rule 68.2 PCT to pay one additional fee was justified.

Order

# For these reasons it is decided that:

The protest according to Rule 68.3(d) PCT is dismissed.

The Registrar:

The Chairman:

A. Nuss

