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D E C I S I O N
of 25 June 2003

Case Number: W 0006/03 - 3.3.4

Application Number: PCT/US01/50502

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Title of invention:
Anti-bacterial plant compositions

Applicant:
Inter American University of Puerto Rico

Opponent:
-

Headword:
Plant compositions/INTER AMERICAN UNIVERSITY OF PUERTO RICO

Relevant legal provisions:
EPC Art. 154(3)
PCT Art. 17(3)(a), 34(3)(a)
PCT R. 13.1, 13.2, 13.13, 40.1, 40.2, 68.2

Keyword:
"Lack of unity *a priori* - (partially no)"

Decisions cited:
W 0013/87, G 0001/89, G 0002/89

Catchword:
-



Case Number: W 0006/03 - 3.3.4
International Application No. PCT/US01/50502

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 25 June 2003

Applicant: Inter American University of Puerto Rico

Representative: DAVID, Michael
6658 Windsor Court
Columbia, MD 21044 (US)

Subject of the Decision: 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 2 July 2002.

Composition of the Board:

Chairman: U. Kinkeldey
Members: M. Wieser
B. Günzel

Summary of Facts and Submissions

I. International patent application PCT/US/01/50502 was filed on 28 December 2001 with twenty-nine claims.

Claims 1, 9, 16 and 26 read as follows:

"1. A pharmaceutical composition comprising a pharmaceutical carrier and at least one compound in isolated or purified form selected from the group consisting of cobaltacene-octgomet and stigmastan-3,5,-diene.

9. A pharmaceutical composition comprising a pharmaceutical carrier and at least one compound selected from the group consisting of galoxolide, benzyl salicylate, eucalyptol and á-pinene.

16. A method of preparing a composition having antimicrobial activity comprising extracting a plant material in an organic solvent, contacting the extracted material with a chromatographic separation system, and eluting the chromatographic separation system with a mobile polar phase to obtain a composition, wherein the plant material is from *Mammea Americana*, *Marchantaceae polymorpha*, or *Callistemon citrinus*, and wherein the composition has antimicrobial activity.

26. A method of inhibiting the growth of a mycobacterium, comprising administering a composition comprising a carrier and at least one compound selected from among cobaltacene-octgomet, stigmastan-3,5-diene, galoxolide, benzyl salicylate, eucalyptol, and á-pinene.

II. On 2 July 2002 the European Patent office (EPO), acting as International Searching Authority (ISA), invited the applicants to pay within a time limit of 45 days five additional search fees pursuant to Article 17(3)(a), Rule 40.1 and 40.3 PCT and issued a partial search report on claims 1 (partly), 3, 4 to 5 (partly), and 26 to 29 (partly). The invitation stated the 6 groups of inventions to which the application was found to relate, namely:

(1) Claims: 1 to 8, 26 to 29(partly)

A pharmaceutical composition comprising a pharmaceutical carrier and at least cobaltacene-octgomet or stigmastan-3,5-diene in isolated or purified form and a method of inhibiting the growth of a mycobacterium using said composition.

(1.1) Claims: 1(partly), 2, 4 to 5(partly), 6 to 8, 26 to 29(partly)

A pharmaceutical composition comprising a pharmaceutical carrier and at least cobaltacene-octgomet in isolated or purified form and a method of inhibiting the growth of a mycobacterium using said composition.

(1.2) Claims: 1(partly), 3, 4 to 5(partly), 26 to 29(partly)

A pharmaceutical composition comprising a pharmaceutical carrier and at least stigmastan-3,5-diene in isolated or purified form and a method of inhibiting the growth of a mycobacterium using said composition.

(2) Claims: 9 to 15(partly), 26 to 29(partly)

A pharmaceutical composition comprising a

pharmaceutical carrier and at least galoxolide and a method of inhibiting the growth of a mycobacterium using said composition.

(3) Claims: 9 to 15(partly), 26 to 29(partly)

A pharmaceutical composition comprising a pharmaceutical carrier and at least benzyl salicylate and a method of inhibiting the growth of a mycobacterium using said composition.

(4) Claims: 9 to 15(partly), 26 to 29(partly)

A pharmaceutical composition comprising a pharmaceutical carrier and at least eucalyptol and a method of inhibiting the growth of a mycobacterium using said composition.

(5) Claims: 9 to 15(partly), 26 to 29(partly)

A pharmaceutical composition comprising a pharmaceutical carrier and at least α -pinene and a method of inhibiting the growth of a mycobacterium using said composition.

(6) Claims: 16 to 25

A method of preparing a composition having antimicrobial activity comprising extracting a plant material in an organic solvent.

The reasons for the non-unity finding of the ISA were:

"It is immediately apparent that the different (groups of) inventions a priori do not share a single general inventive concept as inventions 1-5 relate to pharmaceutical compositions comprising 6 chemically unrelated, known compounds and claim 16 relates to a method preparing an antimicrobial composition in the

form of a plant extract.

In addition, it is noted that a composition comprising stigmastan-3,5-diene and a pharmaceutical carrier is known (e.g., Moreda et al., Journal of Chromatography A, 936, 159-171)."

The ISA noted that all inventions mentioned under item (1), although not necessary linked by a common inventive concept, could be searched without effort justifying an additional search fee. However, since invention (1.1) referred to a compound designated "cobaltacene-octgomet", which name was considered to be so unclear that no meaningful search was possible, the search had been carried out for invention (1.2) only.

III. On 14 August 2002 the applicants paid five additional search fees under protest pursuant to Rule 40.2 PCT and provided a reasoned statement to the effect that the international application complied with the requirement of unity of invention. They submitted that the first five inventions had a special technical feature in common which defined them over the prior art, as requested in Rule 13.2 PCT, namely that they had anti-microbial, in particular anti-mycobacterial, activity. The sixth invention referred to methods for preparation or use of the compositions of inventions 1 to 5.

With the same letter the applicants filed amended pages 3, 4, 8, 14 and 23 of the description and an amended set of claims 1 to 29, wherein the term "cobaltacene-octgomet", which was said to be an obvious error, was replaced by "cobaltocene-octomet".

IV. On 8 November 2002, the ISA communicated to the

applicants the result of its review under Rule 40.2(e) PCT.

With regard to inventions 1 to 5 it was stated that alternative compounds, claimed in one patent application and sharing a common activity, have to have a common structure or belong to a recognized class of chemical compounds, in order to meet the requirements of Rule 13.2 PCT. It was considered that the compounds of inventions (4) and (5), i.e. eucalyptol and α -pinene, which both were well-known terpenes, met these requirements, so that the refund of one additional search fee was ordered. The compounds of combined inventions (4) and (5), as defined by the ISA, and each of the compounds of the first three inventions did not share a structural element or belonged to a recognized class. Invention (6) was found not to share a single general inventive concept with the other inventions.

Thus, the need of the payment of four additional search fees was confirmed.

V. On the same date the ISA transmitted the International Search Report, established on the basis of claims 1 to 29 as originally filed. Claims referring to the compound "cobaltacene-octgomet" (invention (1.1)) were considered to be unsearchable because they were unclear to such an extent that no meaningful search was possible.

VI. The protest fee was paid by the applicants on 9 December 2002 in conformity with Rule 40.2(c) PCT.

On the same date the applicants submitted a letter

wherein they requested that a further search be carried out on the basis of the substitute claims provided on 14 August 2002.

Reasons for the Decision

1. The protest is admissible.
2. According to Rule 13.1 PCT, the international patent application shall relate to one invention only or to a group of inventions so linked as to form a single inventive concept. As stated in Rule 13.2 PCT, this requirement is fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding "special technical features", these being those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

If the ISA considers that the claims lack this unity, it is empowered, under Article 17(3)(a) PCT, to invite the applicant to pay additional fees.

3. Under Article 154(3) EPC the boards of appeal rule on protests against additional fees charged by the ISA under Article 17(3)(a) PCT. Under Rule 40.2(c) PCT they can examine the protest and, to the extent that they find it justified, order total or partial reimbursement of the additional fees.
4. The board has no power to examine the unity of the present invention on the basis of new claims 1 to 29 submitted by the applicants on 14 August 2002. Its

powers derive - as indicated above - from Article 154(3) EPC in conjunction with Rule 40.2(c) PCT, which provide for it to examine the protest. This has to be done on the basis of the documents available when the ISA issued its invitation to pay the additional search fees; there is no provision for amendments during proceedings before the ISA.

5. Lack of unity 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 (cf. decision W 13/87, 9 August 1988).
6. According to Rule 13.3 PCT, the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.
7. The ISA has based its invitation to pay additional search fees on the fact that the international application lacks unity *a priori* as it concerns five different inventions.

Although the ISA mentioned a document which was considered to be novelty destroying for a part of the claimed subject-matter, no objection for lack of unity *a posteriori* has been substantiated.

Rule 40.1 PCT stipulates that the invitation under Article 17(3)(a) PCT to pay additional fees must say why the international application is considered to lack unity. This means it must include a substantiation the applicant can follow.

The reason given by the ISA for its non-unity objection was that the different inventions relate to pharmaceutical compositions comprising chemically unrelated, known compounds, respectively a method for preparing an antimicrobial composition in the form of a plant extract.

Although the substantiation given by the ISA is rather short and not absolutely conclusive, the board considers that the ISA has fulfilled its obligation to substantiate its findings.

8. Four of the five different inventions identified by the ISA refer to pharmaceutical compositions and a use thereof, each comprising a carrier and a different, pharmaceutically active substance. These substances are stigmastan-3,5-diene (invention (1.2)), galoxolide (invention (2)), benzyl salicylate (invention (3)), and eucalyptol or α -pinene (invention (4+5)). The fifth invention is concerned with a method for the production of an antimicrobial composition comprising extraction of plant material with an organic solvent and chromatographic separation of the extracted material.
9. The applicants argue, that the first four inventions are unified by the special technical feature that they have anti-microbial, and in particular anti-mycobacterial activity.

Following the Administrative Instructions of the PCT (see Annex B, Unity of invention, paragraph (f)), which according to the decision of the Enlarged Board of Appeal G 1/89 and G 2/89 (OJ EPO 1991, 155 and 166) are binding to the boards, in a case where the claims, or a single claim, defines alternatives, the requirement of

a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2 PCT, shall be considered to be met when the alternatives are of a similar nature.

When alternatives of chemical compounds are claimed, they shall be regarded as being of similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity, **AND**

(B)(1) a common structure is present, i.e. a significant structural element is shared by all of the alternatives, or

(B)(2) all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

The words "significant structural element is shared by all of the alternatives" under (B)(1) above is defined as meaning that the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art (Annex B, Part 1(f)(ii)).

A "recognised class of chemical compounds" under (B)(2) above is defined as meaning 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. In other words, each member could be substituted for the other, with the expectation that the same intended result would be

achieved (Annex B, Part 1(f)(iii)).

10. The board agrees that the pharmaceutically active substances of the compositions of inventions (1.2), (2), (3) and (4+5), as indicated in point 8 above, meet the requirement of criterium (A).

However, the chemical substances, which are known in the art *per se*, are a sterol (invention (1.2)), a benzopyran-derivate (invention (2)), an ester of an organic acid (invention (3)) and terpenes (invention (4+5)). As such they obviously do not fulfil either of criteria (B)(1) or (B)(2). Accordingly, the requirement of unity of invention is not met.

11. The method of claim 16 is defined by extracting plant material derived from three specific plants with an organic solvent. Thereafter, the extracted material is contacted with a chromatographic separation system. Finally the system is eluted with a mobile polar phase to obtain a composition having antimicrobial activity.

The description on page 4, lines 17 to 25 states that the invention is concerned with the identification and isolation of purified plant fractions and compounds having antimicrobial activity. The plant material is described to be from *Mammea Americana*, *Marchantaceae polymorpha* or *Callistemon citrinus*, i.e the plants listed in claim 16. The method described for obtaining said fractions and substances is essentially the same as claimed in claim 16. On page 8 of the description it is stated that methylene chloride extracts from the plants specified in claim 16 contain the pharmaceutically active compounds contained in the compositions according to inventions (1.2), (2), (3)

and (4+5). It is stated to be an aspect of the invention to provide compositions comprising a pharmaceutical carrier and at least one of these compounds (page 8, lines 26 to 36).

12. Accordingly, the board does not agree with the ISA in this point. The method according to claims 16 to 25 has been specifically designed for the production of the various compositions of claims 1 and 9 (inventions (1.2), (2), (3) and (4+5)), and therefore can be considered as the technical link unifying the subject-matter of claims 16 to 25 with either of the other inventions.

13. Therefore, the board partially follow the ISA's reasoning, according to which the searched subject-matter is not considered as complying with the requirements of unity of invention. Hence, the invitation provided for in Article 34(3)(a) and Rule 68.2 PCT to pay additional search fees is to be regarded as legally effective for groups (1.2), (2), (3) and (4+5) as defined by the ISA, as they do not satisfy the requirement of Rule 40.1 PCT.

Order

For these reasons it is decided that:

One additional search fee shall be reimbursed.

The Registrar:

The Chairwoman:

P. Cremona

U. M. Kinkeldey