

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT



(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference 8951-127-228 | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/US00/27087 | International filing date (day/month/year) 02/10/2000 | Priority date (day/month/year) 29/03/2000 |
| International Patent Classification (IPC) or national classification and IPC A61K35/78 | | |
| Applicant PURDUE RESEARCH FOUNDATION et al. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I Basis of the report
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

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|---|--|
| Date of submission of the demand 10/10/2001 | Date of completion of this report 22.07.2002 |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized officer Winger, R Telephone No. +49 89 2399 8129  |

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/27087

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-42 as originally filed

Claims, No.:

1-66 as originally filed

Drawings, sheets:

1/20-20/20 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:

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the drawings, sheets:

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c):
(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
- the entire international application.
 - claims Nos. 42-66.

because:

- the said international application, or the said claims Nos. 42-66 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet
 - the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
 - the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 - no international search report has been established for the said claims Nos. .
2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:
- the written form has not been furnished or does not comply with the standard.
 - the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims

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| | | | |
|-------------------------------|------|--------|------|
| | No: | Claims | 1-41 |
| Inventive step (IS) | Yes: | Claims | |
| | No: | Claims | 1-41 |
| Industrial applicability (IA) | Yes: | Claims | 1-41 |
| | No: | Claims | |

2. Citations and explanations
see separate sheet

Re Section III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Claims 42-66 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to novelty, inventive step and industrial applicability of the subject-matter of these claims.

Re Section V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2. Prior Art: Reference is made to the following documents cited in the International Search Report
 - D1: PATENT ABSTRACTS OF JAPAN vol. 014, no. 030 (C-678), 19 January 1990 (1990-01-19) & JP 01 268683 A
 - D2: CHEMICAL AND PHARMACEUTICAL BULLETIN, vol. 37, no. 12, 1 December 1989, pages 3255-3263
 - D3: CHEMICAL AND PHARMACEUTICAL BULLETIN, vol. 31, no. 11, 1983, pages 3906-3914,
 - D4: WO 00 57875 A
- 2.1 Document D1 discloses a method to produce tea catechin extracts with reduced levels of EGCg using tannase.
- 2.2 Documents D2 and D3 disclose the use of tannase to hydrolyse gallates from oolong tea and epigallocatechin digallates from green tea, respectively.
- 2.3 Document D4 discloses tea catechin compositions with a reduced EGCg content. However, assuming that the priority claim is valid, the document is not considered to constitute prior art. In the regional phase, document D1 could anticipate the novelty of claims 14-41.

3. Novelty and Inventive Step (Article 33(2) and (3) PCT):

3.1 Independent claim 1 is anticipated by document D1.

3.2 Claims 2-13, relating to a method of producing a tea catechin formulation with reduced EGCg levels, is not novel and inventive with respect to D1, because only specific reaction conditions are selected, which do not seem to be associated with any effect.

3.3 The compositions of claims 14-41, which are only defined by the selection of specific contents, are not novel and inventive with respect to the compositions of D1, because no effect seems to be associated with this selection and, in addition, it is unclear how these compositions are delimited from those of D1.