# PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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# PCT

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing
*(day/month/year)* see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

**FOR FURTHER ACTION**
See paragraph 2 below

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/IB2009/054320 | 02.10.2009 | |

International Patent Classification (IPC) or both national classification and IPC
INV. A61K36/285 A61P31/18 A61P31/12

Applicant
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1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| Name and mailing address of the ISA: | Date of completion of this opinion | Authorized Officer |
|---|---|---|
| European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0<br>Fax: +49 89 2399 - 4465 | see form PCT/ISA/210 | Schnack, Anne<br>Telephone No. +49 89 2399-8149 |

**WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2009/054320

**Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. (means)

      ☐ on paper

      ☐ in electronic form

   b. (time)

      ☐ in the international application as filed

      ☐ together with the international application in electronic form

      ☐ subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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. 3, 7, 8(completely); 5, 6, 10-16(partially)

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search *(specify)*:

☐ 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 *(specify)*:

☒ no international search report has been established for the whole application or for said claims Nos. 3, 7, 8(completely); 5, 6, 10-16(partially)

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ See Supplemental Box for further details

## Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☐ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   **see separate sheet**

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1, 2, 4, 9(completely); 5, 6, 10-16(partially)

## Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | |
| | No: | Claims | 1, 2, 4, 9(completely); 5, 6, 10-16(partially) |
| Inventive step (IS) | Yes: | Claims | |
| | No: | Claims | 1, 2, 4, 9(completely); 5, 6, 10-16(partially) |
| Industrial applicability (IA) | Yes: | Claims | 1, 2, 4, 9(completely); 5, 6, 10-16(partially) |
| | No: | Claims | |

2. Citations and explanations

   **see separate sheet**

Reference is made to the following documents:

D1 US 2005/129780 A1 (HOLCOMB-HALSTEAD TERRI L [US] ET AL) 16 June 2005 (2005-06-16) cited in the application

D2 WO 2004/112692 A2 (AMAZON BIOTECH INC [US]) 29 December 2004 (2004-12-29)

D3 PANDEY ET AL: "Saussurea costus: Botanical, chemical and pharmacological review of an ayurvedic medicinal plant"JOURNAL OF ETHNOPHARMACOLOGY, ELSEVIER SCIENTIFIC PUBLISHERS LTD, IE LNKD- DOI:10.1016/J.JEP.2006.12.033, vol. 110, no. 3, 13 March 2007 (2007-03-13) , pages 379-390, XP005931818ISSN: 0378-8741

D4 CHEN H C ET AL: "Active compounds from Saussurea lappa Clarks that suppress hepatitis B virus surface antigen gene expression in human hepatoma cells." May 1995 (1995-05) , ANTIVIRAL RESEARCH MAY 1995 LNKD- PUBMED:7486962, VOL. 27, NR. 1-2, PAGE(S) 99 - 109 , XP002582907ISSN: 0166-3542

**Section IV**

**Unity**

Remarks under Rule 13.1 PCT:

This Authority has identified (at least) four inventions:

**Invention 1, Claims 1, 2, 4, 9 (entirely), 5, 6, 10-16 (partially)**

Use of a herbal composition in the preparation of a medicament for the treatment of a subject infected with HIV, the composition comprising an extract of the plant Aucklandia-(Costus Root).

**Invention 2, Claim(s) 3 (entirely), 10-16 (partially)**

Use of a herbal composition in the preparation of a medicament for boosting the immune system of a subject, the composition comprising an extract of the plant Aucklandia-(Costus Root).

**Invention 3, Claims 5, 6, 10-16 (partially)**

Use of a herbal composition in the preparation of a medicament for stimulating bone marrow formation in a non-HIV infected subjects, the composition comprising an extract of the plant Aucklandia-(Costus Root).

**Invention 4, Claims 7, 8 (entirely), 5, 6, 10-16 (partially)**

Use of a herbal composition in the preparation of a medicament for the treatment of conditions selected from diabetes, liver disease, viral hepatitis, fatty liver, liver cirrhosis, liver cancer, herpes zoster, jaundice, and herpes simplex, the composition comprising an extract of the plant Aucklandia-(Costus Root).

The four inventions as listed above do not combine in a unitary manner as required by Rule 13 PCT, the reasons being as follows:

Extracts of the plant Aucklandia-(Costus Root) for medical purposes have been known for many, many years and is part of the traditional Chinese medicine, (see Pandey et al (2007) abstract).

Conditions which have been treated with extracts of this plant are e.g. inflammation, cancer, asthma, ulcer etc., (see Pandey et al (2007) abstract). Immunomodulating as well as hepatoprotective properties are also described, (see Pandey et al, page 385).

The present four groups of inventions are not linked through a novel and inventive common concept, because the diseases claimed are not linked by a novel and inventive special technical feature. Also no corresponding special technical features in the sense of Rule 13.2 PCT can be identified by this Authority: Treatment of HIV-infected subject does not combine with treatment of non-HIV infected patients in need of boosting the immune system or with patients suffering from the diseases according to present claim 7. Neither does the treatment of non-HIV infected in need of stimulation of bone marrow formation combine with such subject matter. Not even the immunomodulatory or antiviral properties of the plant extract can serve as unifying concept, since it is already known that Aucklandia possesses such properties, (see Pandey et al, 5.6, and Chen et al (1994), abstract).

Thus, each of the conditions presently claimed is considered to be a distinct invention, which is not linked in any novel and inventive manner to the other diseases claimed.

Sine no further search fees have been paid, this opinion is based solely on invention 1.

**Section V**

**V.1. Novelty**

Remarks under Article 33(2) PCT:

The present application is essentially directed to compositions (claims 14-16) comprising an extract of the plant Aucklandia-(Costus root), and uses of such for treating subjects infected with HIV, (independent claims 1, 2, 4 and 9).

Treatment of HIV infection as well as AIDS and HIV associated symptoms with extracts of the plant Aucklandia-(Costus Root) has already been described by the prior art, (see D1 and D2, the passages cited in the search report).

In this context it is pointed out that even though these documents only disclose extracts of Aucklandia as part of a herbal composition including other plant extract as well, this does not change that D1 and D2 discloses subject matter falling within the present independent claims 1, 2, 4 and 9.

The compositions according to present claims 14-16 are also not considered novel in view of the fact that aqueous and dry extracts of Aucklandia have been used as medicaments for thousands of years, (see also D3, 3. Ethnobotany, Table 3 and 5. Pharmacology).

## V.2. Inventive step

Remarks under Article 33(3) PCT:

The antiviral activity of Aucklandia is already known, (see D4, passages mentioned in the search report). Thus, any novel subject matter falling within the scope of the present claims does not appear to reside in an inventive teaching, because it appear to be obvious to examine the anti-viral activity against HIV virus.

## V.3. Industrial applicability

The present subject matter fulfils the requirements for industrial applicability.