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Australian Government
IP Australia

Address: A.P.T. Patent and Trade Mark Attorneys
PO Box 222
MITCHAM SA 5062
Australia

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Patent Examination Report No. 1

Application Details

Patent Application No.: 2008273073
Applicant/s: Universiti Putra Malaysia
Your reference: 4847
Earliest Priority Date: 11 July 2007
Examination Request Date: 18 January 2012

Your application has been examined under Section 45 of the *Patents Act 1990*. I consider that the application does not meet the requirements of the Act for the reasons indicated below.

Actions you can take

You have **21 months** from the date of this report to overcome all my objection(s) otherwise your application will lapse.

You will need to pay a monthly fee for any response you file after 12 months from the date of the first report.

You will also need to pay any annual continuation fees that apply. Information about fees may be obtained by phoning 1300 651 010 or by visiting www.ipaustralia.gov.au.

Basis of the report

In examining your application I have taken into account:

- the PCT pamphlet and amendments already made under the PCT Articles



I have examined this application on the basis of the claims as amended under Article 19. However, you may wish to correct the non-sequential page/claim numbering caused by the Article 19 amendments

Statement of Novelty, Inventive Step and Patentable Subject Matter

Novelty/Inventive Step	Claim No. NONE	Yes
	Claim No. 1-4, 8-10, 12	No
Patentable Subject Matter	Claim No. 1-4, 8-10, 12	Yes
	Claim No. NONE	No

Documents Cited or Considered Relevant

D1 : WO 2005/070442 A1 (COUNCIL OF SCIENTIFIC & INDUSTRIAL RESEARCH) 04 August 2005 *
Category: X Claims: 1-4, 8-10, 12

D2 : IRINE, R et al. Antioxidant and Hypocholesterolemic Effects of Elaeis guineensis Frond Extract on Hypercholesterolemic Rabbits. ASEAN Food J. 2003, Vol. 12, No. 3, pages 137-147. *
Category: X Claims: 1-4, 8-10, 12

D3 : ABEYWARDENA, M et al. Polyphenol-Enriched Extract of Oil Palm Fronds (Elaeis guineensis) Promotes Vascular Relaxation via Endothelium-Dependent Mechanisms. Asia Pacific J. Clin. Nutr. 2002, Vol. 11, No. Suppl., pages S467-S472. *
Category: X Claims: 1-4, 8-10, 12

D4 : BRAGA, FC et al. Angiotensin-Converting Enzyme Inhibition by Brazilian Plants. Fitoterapia. April 2007, Vol. 78, pages 353-358. *
Category: X Claims: 1-4, 8-10, 12

D5 : SALLEH, MN et al. Inhibition of Low-Density Lipoprotein Oxidation and Up-Regulation of Low-Density Lipoprotein Receptor in HepG2 Cells by Tropical Plant Extracts. J. Agric. Food Chem. May 2002, Vol. 50, No. 13, pages 3693-3697. **
Category: X Claims: 1-4, 8-10, 12

D6 : TKDL Abstract No. AN2/391D. (KHAN, MNG. Khazaain-al-Advia. Lahore: Sheikh Mohd Basheer & Sons, 1911, Vol. II, pages 420-421.) ****
Category: X Claims: 1-4, 8-10, 12

D7 : TKDL Abstract No. FA1/169I. (KHAN, MA. Muheet-e-Azam. Kanpur: Matba Nizami, 1899, Vol. IV (Part I), pages 90-91.) ^
Category: X Claims: 1-4, 8-10, 12

* Cited in the EP FER dated 27 July 2011 for Publication No. 2170105.

** Cited in the US FER dated 04 February 2013 for Publication No. 2011/0003019.

**** Cited in the Third Party Observation lodged by the Council of Industrial and Scientific Research, India on 10 January 2011 under s 27. Submitted as Exhibit 1.

^ Cited in the Third Party Observation lodged by the Council of Industrial and Scientific Research, India on 10 January 2011 under s 27. Submitted as Exhibit 2.

Note that this report has cited non-patent literature document/s. Copies of non-patent literature document/s can be requested for a fee (see Patent Regulations, schedule 7, fee item 234) by emailing assist@ipaustrialia.gov.au.

Please provide the citation details and associated patent application number with your request. Note that because of copyright restrictions we can only provide copies of hard copy books, journals and newspapers (see the Australian Patent Office Manual of Practice and Procedure at part 2.13.14 Copying of Material and Copyright Implications). However copies of any remaining documents should be readily obtainable from known electronic database sources.

Special categories of cited documents:

X: The claimed invention cannot be considered novel under subsection 7(1) in light of the document and/or cannot be considered to involve an inventive step under subsection 7(2) of the Act in light of the common general knowledge considered together with the document.

Novelty and Inventive Step

- 1 Claims 1 and 8 lack novelty (and an inventive step) in light of each of D1 and D2, considered independently. Claims 2-4, 9, 10 and 12 either lack both novelty and an inventive step or lack an inventive step in light of each of D1 and D2.

D1 discloses pharmaceutical compositions comprising extracts of *Amorphophallus camplanulatus* and methods of preparation and use thereof for the treatment of hyperlipidemia, atherosclerosis and obesity. (see Abstract) In accordance with the preparative methods of D1, leaves rhizome and/or aerial parts of the plants used are dried, powdered and extracted with an alcohol (which is ethanol in one embodiment) and concentrating and subsequently lyophilising the extract to remove the solvent. (see p 10) Compositions according to D1 are considered suitable for oral administration. (see p 9, ln 11-12)

D2 discloses methanolic extracts obtained from fronds of *Elaeis guineensis*. The extracts were obtained by chopping, oven drying and blending fresh oil palm fronds, followed by extraction with methanol and vacuum drying. (see p 138) The oil palm frond extract obtained in this way was included in rabbit pellets in order to test its potential hypocholesterolemic effects. (see p 139) The studies of D2 demonstrated antioxidant and hypocholesterolemic effects obtained by administration of the oil palm frond extract in this manner. (p 145)

Consequently, each and every feature of Claims 1 and 8 is disclosed in each of D1 and D2 and so these claims are anticipated by each of D1 and D2.

Claims 2-4 (appended to Claim 1) and 9, 10 and 12 (appended to Claim 8) add features which are disclosed in one or both of D1 and D2 and/or represent common general knowledge in the art which a person skilled in the art would routinely apply to the subject matter of Claim 1 or 8 respectively.

- 2 Claim 1 lacks novelty (and an inventive step) in light of each of D6 and D7, considered independently. Claims 2-4 either lack both novelty and an inventive step or lack an inventive step in light of each of D6 and D7. Claims 8-10 and 12 lack an inventive step in light of each of D6 and D7, considered independently.

D6 discloses a liquid preparation of herbal drugs for oral administration extracted from vegetative buds of *Phoenix dactylifera Linn.* with water. Such compositions are said to be useful as a 'cardiotonic' or for treatment of 'palpitation'.

D7 discloses the use of a juice obtained by straining fresh herbs of *Phoenix dactylifera Linn.* as a 'cardio-tonic' and for treatment of 'palpitations' by oral administration. 'Straining' in this context would typically involve the use of water, a relevant polar solvent.

Consequently, each and every feature of Claim 1 is disclosed in each of D6 and D7 and so both D6 and D7 anticipate this claim.

Claims 2-4 (appended to Claim 1) add features which are disclosed in one or both of D6 and D7

and/or represent common general knowledge in the art which a person skilled in the art would routinely apply to the subject matter of Claim 1.

The method of Claim 8 differs from those of D6 and D7 in that D6 and D7 do not disclose the specific extraction steps of pre-treatment of the foliage or of concentration of the resultant extract. However, such process steps are extremely commonplace in the art and a person skilled in the art would routinely apply such methods in preparing compositions according to either D6 or D7.

Claims 9, 10 and 12 (appended to Claim 8) add features which represent common general knowledge in the art which a person skilled in the art would routinely apply to the subject matter of Claim 8 and therefore do not contribute to providing an inventive step.

- 3 Claim 8 lacks novelty (and an inventive step) in light of each of D3-D5, considered independently. Claims 9, 10 and 12 either lack both novelty and an inventive step or lack an inventive step in light of each of D3-D5. Claims 1-4 lack an inventive step in light of each of D3-D5.

D3 discloses extracts of *Elaeis guineensis* fronds obtained by washing, cutting, oven drying and grinding the fronds then extracting them with methanol and subsequently removing the solvent under vacuum. (p S468) *In vitro* testing indicated that these palm frond extracts possessed substantial vasorelaxant properties. (p S471)

D4 discloses extracts of *Phoenix roebelinii* leaves obtained by washing, drying and powdering the leaves then conducting extraction with ethanol, which is then removed under vacuum. (see p 355) *In vitro* studies showed significant inhibition of the angiotensin-converting enzyme (ACE) by this extract. (see p 357)

D5 discloses extracts of *Elaeis guineensis* fronds obtained by methanol extraction. In order to obtain the extracts of D5, the fronds were rinsed, dried, cut and freeze dried then ground into powder and extracted with methanol. The organic phase was then filtered and the methanol removed under vacuum. (see pp 3693, 3694) *In vitro* studies indicated that these extracts inhibited oxidation of low-density lipoproteins (LDLs), a process known to contribute to atherosclerosis. (see pp 3693 and 3695 (especially Table 1))

Thus, D3-D5 each disclose every feature of Claim 8.

Claims 9, 10 and 12 (appended to Claim 8) add features which are disclosed in one or more of D3-D5 and/or represent common general knowledge in the art which a person skilled in the art would routinely apply to the subject matter of Claim 8.

The composition of Claim 1 differs from those of D3-D5 only in that the compositions of D3-D5 are not specifically stated to have been included in a comestible composition and it is not apparent from any of these documents that the conditions used to obtain the extracts of D3-D5 would render them safe for consumption. However, it would be obvious to a person skilled in the art that oral administration would be a suitable means of administering extracts according to any one of D3-D5 and a person skilled in the art would routinely adapt the procedures according to D3-D5 to ensure that the compositions in question were safe for such a use by using methods which are standard practice in the art.

Claims 2-4 (appended to Claim 1) add features which represent common general knowledge in the art which a person skilled in the art would routinely apply to the subject matter of Claim 1 and therefore do not contribute to providing an inventive step.

Other Issues

- 4 As a result of the amendments made under Art 19 of the PCT, the specification does not comply with Sch 3, cl 5(2) and (4) in that the claim pages are numbered 23 and 24 rather than 21 and 22 and there are currently eight claims numbered 1-4, 8-10 and 12 rather than 1-8.

How to contact us

Examiner: Alan Criddle
B2 - Chem/Biotech
Patent Examination A
(02) 6283 2846

Corporate Telephone: 1300 651 010
(9am-5pm Mon- Fri)

Fax: (02) 6283 7999

Supervisor: Cassandra Mitchell
Phone: (02) 6283 2643

Mail: IP Australia
PO Box 200
Woden, ACT 2606

Email: assist@ipaaustralia.gov.au

Website: www.ipaustralia.gov.au



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