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GOVERNMENT OF INDIA  
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6756/CHEMP/2009

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Date : 23/12/2014

Letter No.:-CHEM/2015/

To,  
Shri.Dr. Gopakumar G. Nair  
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SUB : Examination Report

APPLICATION NUMBER : 6756/CHEMP/2009  
DATE OF FILING : 17/11/2009  
DATE OF REQUEST FOR EXAMINATION : 17/11/2009  
DATE OF PUBLICATION : 05/03/2010

With reference to the RQ No. 7124/RQ-CHE/2009 Dated 17/11/2009 in the above mentioned application for Grant of Patent ,  
a) Examination has been conducted under Section 12 and 13 of the Patents Act 1970 , The following objections are hereby communicated

b) Objections :

The claims lack novelty in accordance with the provisions of sec 13 of the Patents Act 1970 in view of the cited document. US2006/167097 discloses a fraction of amoora rohituka (synonym for Aphanamixis polystachya) which is also mentioned in page 4 of the instant application where the plant is enriched in amooranin compounds, for the treatment of inflammatory? diseases (see [0075]; e.g lupus, rheumatoid arthritis). The extract is derivable from any plant part wherein the bark appears to be the preferred part. Compositions comprising said extract are disclosed under [0039] and [0056]-[0066]. Combinations with further active compounds, inter alia further antiinflammatory agents are mentioned in [0073]. However, the antiinflammatory action of amoora rohituka is already known from D1. In the light of D1 the subject-matter of claims are not novel.

The claims lack inventive step in accordance with the provisions of sec 2(1)(ja) of the Patents Act 1970.

D1-US2006/167097 discloses a fraction of amoora rohituka (synonym for Aphanamixis polystachya) which is also mentioned in page 4 of the instant application where the plant is enriched in amooranin compounds, for the treatment of inflammatory? diseases (see [0075]; e.g lupus, rheumatoid arthritis). The extract is derivable from any plant part wherein the bark appears to be the preferred part. Compositions comprising said extract are disclosed under [0039] and [0056]-[0066]. Combinations with further active compounds, inter alia further antiinflammatory agents are mentioned in [0073]. However, the antiinflammatory action of amoora rohituka is already known from D1.

D2 - SARKAR M ET AL: "PHARMACOGNOSTIC EVALUATION OF APHANAMIXIS-POLYSTACHYA SEED DRUG" JOURNAL OF ECONOMIC AND TAXONOMIC BOTANY, SCIENTIFIC PUBLISHERS, JODHPUR., IN, vol. 15, no. 1, 1991, pages 121-127, XP009095420 ISSN: 0250-9768 discloses that the seed oil fraction of" Aphanamixis polystachya is used as a stimulating liniment in rheumatism.

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D3-HARMON A.D. ET AL.: "The structure of rohitukine, the main alkaloid of Amoora rohituka (syn. Aphanamixis polystachya, Meliaceae)" TETRAHEDRON LETTERS, vol. 8, 1979, pages 721-724, XP002468410 U.K.



In view of the cited documents D1-D3 , the combinations with further antiinflammatory agents and the extraction process are not inventive .

- 3 The present application falls within the scope of Section 3(p) of the Patents Act, 1970.Refer TKDL website where references are given for the treatment of inflammation using Aphanamixis polystachya .Around 23 references are got from the TKDL database (reference enclosed).

D1- Siddhayogasa?graha? EDN1st 1978 page 64

Formulation ID RG10/100B which refers to a formulation containing Aphanamixis polystachya for the treatment of inflammation.

D2-Ras?m?tam this book contains reference from 1000 B.C to 20th century page 714

Formulation ID AK15/169D

D3- Siddhaprayogasa?graha? part I

Formulation ID RS22/723A

D4-yurveda page 261

Formulation ID RG12/559B

D5-Gadanigraha page 774-775

Formulation ID HG/2413E

The claimed composition from Aphanamixis polystachya for the treatment of inflammation is known traditionally from the Indian system of medicines which is also disclosed in page 4 and 5 of the specification. Hence not allowed u/s 3(p) of The Patents Act 1970.(Refer the enclosed document )

- 4 In the absence of synergistic effect, if any, claims 1-10 fall within the scope of section 3(e) of The Patents Act, 1970.
- 5 The subject matter of claim 13 is not patentable under section 3(i) of The Patents Act, 1970 as it claims method of medical treatment.
- 6 The subject matter of claims 1,6-8 are indirectly related to method of medical treatment. Therefore, the said claims fall within the scope of Section 3(i) of the Patents Act, 1970.
- 7 The subject matter of claims are not patentable under section 3(c) of The Patents Act, 1970 .It is clear from the description that extract product is isolated from said plant Aphanamixis (refer Page 11) ,which is naturally occurring in the plant.Hence not patentable.
- 8 The claims are though related to a product ,the product is extracted from different plant material (refer claim 2 )hence not allowable under the provisions of the Section 3(j) of the Patents (Amendment) Act 2005.
- Attention of the applicant is invited towards Section 6 of Biodiversity Act, 2002 which mandates that if biological material procured from India is used in an application for patent, permission and other information for making application for patent should
- 9 be obtained from the National Biodiversity Authority, Relevant application form (Form 3, Rule 18) for such permission is available in website of National Biodiversity Authority. Form 1 of Patent Act should be completed w.r.t column 9 (iii). Source and geographical origin of the biological material used should be given in the specification in accordance with section 10(4)(d)
- 10 Application number and date shall be mentioned in Form 3 Form 5 and Form 18.
- 11 Application number and applicant's name shall be stated at the top-left corner of each drawing sheet.
- Details regarding the search and/or examination report including claims of the application allowed, as referred to in Rule 12(3) of the Patent Rule, 2003, in respect of same or substantially the same invention filed in all the major Patent offices along with
- 12 appropriate translation where applicable, should be submitted within a period of Six months from the date of receipt of this communication as provided under section 8(2) of the Indian Patents Act.
- Details regarding application for Patents which may be filed outside India from time to time for the same or substantially the same
- 13 invention should be furnished within Six months from the date of filing of the said application under clause(b) of sub section(1) of section 8 and rule 12(1) of Indian Patent Act.
- You are requested to comply with the objections by filing your reply by way of explanation and/or amendments within 12 months
- c) from the date of issue of FER failing which you application will be treated as "Deemed to have been abandoned" under section 21(1) of the Act. The last Date is 23/12/2015.

- d) You are advised to file your reply at the earliest so that the office can further proceed with application and complete the process within the prescribed period.

**(N R Meena)**

Deputy Controller of Patents & Designs

**NOTE : All Communications to be sent to the Controller of Patents at INTELLECTUAL PROPERTY BUILDING G.S.T. Road, Guindy Chennai-600032.**

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