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Letter No.:-CHEM/2015/

Date : 22/01/2015

To,
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SUB : Examination Report

APPLICATION NUMBER : **1294/CHENP/2010**
DATE OF FILING : 08/03/2010
DATE OF REQUEST FOR EXAMINATION : 08/03/2010
DATE OF PUBLICATION : 03/02/2012

With reference to the RQ No. 1538/RQ-CHE/2010 Dated 08/03/2010 in the above mentioned application
a) for Grant of Patent , 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 documents.

D1-US6413553 discloses herbal formulation comprising Piper betel extracts formulated with pharmaceutically acceptable carriers and the Piper betel leaf is extracted with water and further additives that are combined with the Piper betel extract can be starch-gelatin paste and a binder. The composition may be administered orally and that the ratio of Piper betel extract to the other extract in the composition is 1:1 to 1 :5, which anticipates the ranged claimed in the instant application. The formulation comprising Piper betel extract is administered in a dosage form to a patient and is used to treat humans.

D2- Muthu et al Indian J Pharmacology April 2006; Vol38, Issue 2, 131-2 teaches administering a methanol extract of Dolichos biflorus, wherein the part of the Dolichos biflorus extracted is the whole plant (which reads on leaves, since the whole plant contain leaves) in an amount of 200 mg/kg or 400

mg/kg, given to rabbits in combination with food (which reads on dietary forms), wherein the methanol extract of *Dolichos biflorus* has antioxidant activity. The extract does not require any additional ingredients.

D3- Arambewela et al. International Journal of Food Science and Technology 2006, 41 (Supplement 1), 10-14 teaches that an ethanol extract of Piper betle leaves has antioxidant activity. Arambewella further teaches that the ethanol extract of Piper betle leaves can be added to food, including aloe gel (which reads on dietary forms and also reads on gel), and can be combined in an amount of 0.2 mg/mol r 0-50 micrograms/m(lwhich reads on the amounts claimed in the instant application, since the amounts can be adjusted to provide the amounts in the percentage claimed). The extract does not require any additional ingredients.

In view of the cited documents the composition containing the herbal extract of Piper and *Dolichos* for treatment of humans is known in the art. Hence claims lack novelty.

The claims lack inventive step in accordance with the provisions of sec 2(1)(ja) of the Patents Act 1970. D1-US6413553 discloses herbal formulation comprising Piper betel extracts formulated with pharmaceutically acceptable carriers and the Piper betel leaf is extracted with water and further additives that are combined with the Piper betel extract can be starch-gelatin paste and a binder. The composition may be administered orally and that the ratio of Piper betel extract to the other extract in the composition is 1:1 to 1:5, which anticipates the ranged claimed in the instant application. The formulation comprising Piper betel extract is administered in a dosage form to a patient and is used to treat humans. D2- Muthu et al Indian J Pharmacology April 2006; Vol38, Issue 2, 131-2 teaches administering a methanol extract of *Dolichos biflorus*, wherein the part of the *Dolichos biflorus* extracted is the whole plant (which reads on leaves, since the whole plant contain leaves) in an amount of 200 mg/kg or 400 mg/kg, given to rabbits in combination with food (which reads on dietary forms), wherein the methanol extract of *Dolichos biflorus* has antioxidant activity. The extract does not require any additional ingredients. D3- Arambewela et al. International Journal of Food Science and Technology 2006, 41 (Supplement 1), 10-14 teaches that an ethanol extract of Piper betle leaves has antioxidant activity. Arambewella further teaches that the ethanol extract of Piper betle leaves can be added to food, including aloe gel (which reads on dietary forms and also reads on gel), and can be combined in an amount of 0.2 mg/mol r 0-50 micrograms/m(lwhich reads on the amounts claimed in the instant application, since the amounts can be adjusted to provide the amounts in the percentage claimed). The extract does not require any additional ingredients. In combined view D1-D3 it would have been obvious to modify the composition used in the method taught by D2 by combining a methanol extract of *Dolichos biflorus* plant (including leaves) with an ethanol extract of Piper betel leaves because at the time the invention was made, it was known that a methanol extract of *Dolichos biflorus* plant (including leaves) and an ethanol extract of Piper leaves were useful antioxidants that could be combined with food and orally consumed, as clearly taught by the above references. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. Thus claims lack inventive step.

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 obesity using Piper betle and *Dolichos biflorus* composition is given. Around 49 references are taken from the TKDL database (reference enclosed). D1-Nigha??uratr??kara? EDN 1868 page 1110 Formulation ID VK2/715 which refers to a formulation containing *Dolichos biflorus* for the treatment of obesity. D2-Vagasena page 495 Formulation ID AK11/1955 D3-VK1/707A The claimed composition from Piper and *Dolichos* for the treatment of obesity is known traditionally from the Indian system of medicines which is also disclosed in the specification. Hence not allowed u/s 3(p) of The Patents Act 1970.(Refer the enclosed document)

In the absence of synergistic effect, if any, claims 1-13, 17-19, 22 fall within the scope of section 3(e) of The Patents Act, 1970. Since the claimed composition appear to have been obtained by a mere admixture resulting only in an aggregation of the properties of the components without any synergistic effect.

5 The subject matter of claims 14-16 are not patentable under section 3(i) of The Patents Act, 1970 as it claims method of medical treatment.

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 be obtained from the National Biodiversity

6 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)

7 Source & Geographical origin of Biological materials in the specification should be disclosed.

8 Application number and date shall be mentioned in Form 3 and Form 5.

9 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
10 filed in all the major Patent offices along with 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
11 or substantially the same 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
c) amendments within 12 months from the date of issue of FER failing which your application will be treated as "Deemed to have been abandoned" under section 21(1) of the Act. The last Date is 22/01/2016.

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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