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Letter No.:-CHEM/2014/

Date : 20/03/2014

To,
DR. I. S. BHATTACHARYA C/O D. P. AHUJA & CO.,
53 SYED AMIR ALI AVENUE, CALCUTTA 700 019,
WEST BENGAL, INDIA

SUB : Examination Report

APPLICATION NUMBER : 497/kolnp/2009

DATE OF FILING : 05/02/2009

DATE OF REQUEST FOR EXAMINATION : 28/07/2010

DATE OF PUBLICATION : 15/05/2009

With reference to the RQ No. 3379/RQ-KOL/2010 Dated 28/07/2010 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 declaration in Form-1 regarding the use of biological material from India is cancelled out by the applicant. But the specification does not state the source and geographical origin of the biological materials used in the present alleged invention (Salix ssp and Andrographis paniculata extracts). The specification should be amended by way of incorporation of a separate heading/paragraph at the beginning of the description that the biological materials used in the instant alleged invention are not from India and should clearly specify the country of source and geographical origin of the same as per CGPDTM's Office Order No. 26 dated 2nd July, 2012 failing which a permission for making such an application for patent should be obtained from the National Biodiversity Authority under section 6 of The Biological Diversity Act. Furthermore, it may be noted that all the plants, whose extracts have been used in the present alleged invention (Salix ssp and Andrographis paniculata extracts) are extensively grown in India also. Willows, sallows, and osiers form the genus Salix, around 400 species of deciduous trees and shrubs, found primarily on moist soils in cold and temperate regions of the Northern Hemisphere. Most species are known as willow, but some narrow-leaved shrub species are called osier, and some broader-leaved species are referred to as sallow. Andrographis paniculata is an annual herbaceous plant in the family Acanthaceae, native to India and Sri Lanka and some other Asian countries like Malaysia. As an Ayurveda herb it is known as Kalmegh or Kalamegha, meaning "dark cloud".

- 2 This office is in agreement with the International Preliminary Report on Patentability (IPRP) drawn on the corresponding PCT application that claims 1-6 are not novel and claims 1-7 do not involve an inventive step in view of the teachings of the prior art documents cited in the said IPRP. The deficiencies

mentioned in that report give rise to objections under the corresponding provisions of the Indian Patents Act. This office bears the same view as the IPRP regarding the relevant portions of the cited prior art documents and corresponding argumentation as given in the said report which are detrimental to the patentability of the said claims. Therefore the said claims are not allowable under section 2(1)(j) of the Act.

3 Without prejudice to the observation under paragraph 2, claims 1-7 attract the provisions of such clause (e) of section 3 of the Act and hence are not patentable.

4 Without prejudice to the observation under paragraph 2, use claim 7 is beyond the scope of invention within the meaning of section 2(1)(j) of the Act and therefore is not patentable.

The observation under paragraph 2 notwithstanding, claims 1-7 attract the provisions of such clause (p) of section 3 of the Act for being traditional knowledge of India and hence are not patentable. In Traditional Knowledge Digital Library (TKDL) there are several references where *Andrographis paniculata* and *Salix* species *Salix caprea* Linn and *Salix alba* Linn have been used for the treatment of Rheumatism, Arthralgia, Oedema/Inflammation, Pain, all types of Stiffness of Joints, Acute Gout, Lumbago, Sciatica, Gout, Pleurodynia, intercostal neuralgia, Immunosuppressive/Emaciating disease, Stiffness loss of movement of leg and used as anti-inflammatory, Analgesic restoring normal sensation and Immuno potentiators/Anti-ageing/Anti-oxidant through oral administration or as directed by physician in the Indian systems of Medicine, since long. Hence, there does not seem to be any novelty or inventive step involved

5 in the claims made in the above referred patent application. Please see the following references: (a) Pandita Narahari; Rajanighantauh, Edited with Hindi Commentary by Indradco Tripathi; Krishnadas Academy, Varanasi, Edn. 2nd, 1998, Pg 266, Formulation ID: RS8/467, Formulation Name: Kiratikta Guna. (b) Mohammad Najmul Ghani Khan; Khazaain-ai-Advia, Vol. 1 (20th century AD), Nadeemm Yunus Printer I Sheikh Mohd Basheer & Sons, Lahore, 1911 AD, Pg 915, Formulation ID: NA2/483B, Formulation Name: Usarah Bed. (c) Lankapatiravana; Arkaprakasah - Edited and translation by Indradeva Tripathi; Krishnadas Academy, Varanasi, Edn. 1st, 1995, Pg 50, Formulation ID: AK14/81A, Formulation Name: Vetasa Arka Gunah. It is to be noted herein that a representation under section 25(1) has been filed by Council of Scientific & Industrial Research against the instant application, which shall be communicated to your office in due course.

6 The term "according to" as used in the dependent claims should be replaced by "as claimed in claim/s".

Title page of the specification (Form-2) should be filed in duplicate to this office along with a petition under rule 137 of the prevailing Indian Patents Rules. Moreover the last claim page should be signed by an authorised signatory with date (name of the signatory should be given) at the end of the claims.

8 Preamble to the claims should be given in prescribed manner.

9 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 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.

10 Details regarding application for Patents which may be filed outside India from time to time for the same 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.

c) You are requested to comply with the objections by filing your reply by way of explanation and/or 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 20/03/2015.

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.

(Dr Dilip Kumar Chakraborty)

Dy. Controller of Patents & Designs

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