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**Date : 26/12/2013**

**Letter No.:-CIEM/2015/**

To,  
K & S PARTNERS  
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OPPOSITE PENINSULA CORPORATE PARK,  
OFF G.K. MARG, LOWER PAREIL,  
MUMBAI-400013

**SUB : Examination Report**

APPLICATION NUMBER : 255/MUM/2007  
DATE OF FILING : 12/02/2007  
DATE OF REQUEST FOR EXAMINATION : 30/03/2009  
DATE OF PUBLICATION : 08/05/2009

With reference to the RQ No. 772/RQ-MUM/2009 Dated 30/03/2009 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 :

Reference is made to following documents; D1; 510/DI1/1996 D2; US6417349 Subjeet-matter claimed in claims 1,8,17 is not meeting requirement of section 2 (1) (j) of Patents Act being obvious over documents D1-D2; Document D1 teaches ?A process for the isolation of fraction containing sixteen constituents such as flavonoids & glycosides possessing anaptogenic activity from plant Centella Asiatica?, the process involves crushing and homogenising fresh whole plant of C. Asiatica, extracting the said homogenised plant using an aqueous alcohol, concentration of said aqueous alcoholic extract to minimum volume by conventional method and partitioning with different organic solvents and subjecting the polar fraction to conventional chromatographic method employing silica gel of mesh size 230-400 ( abstract); The glycoside fraction showing presence in the range of 0.8-25.4 % as monitored by preparative high pressure liquid chromatography (HPLC), the solvents used includes methanol, ethanol, propanol, butanol, the concentrate also partitioned with hexane, chloroform, ethylacetate, butanol, in increasing polarity ( description, claims 1-5); Document D2 describes a water-soluble extract of asiaticoside and madecassoside from Centella asiatica by an aqueous alcohol extract cold precipitation , extracting with an a halogenide solvent for layers separation , extracting the aqueous layers with higher alcohol, washing the

alcoholic extract with NaOH and water, concentration the extract and crystallization with ethyl acetate;

2 Subject-matter claimed in claims 2,5 are mere statements does not disclose technical feature of the invention therefore not meeting requirement of section 10 (4) ( c) of Patents Act. Subejet-matter claimed in claim 17 is meeting requirement of Section 10 (4) ( c) of Patents Act ,

3 **Subejet-matter claimed in claim 1-7, 8-16 is not patentable u/s 3 (p) of Patents Act. Your attention has been drawn to the pregrant opposition filed under section 25(1) of the Act in this application. Exhibit 1:(pg. no. 05-06) refers to a formulation containing Centella asiatica (Linn.) as a single ingredient used as an Intellect promoting and for the treatment of Neurological diseases and Psychosis/Insanity/Mania through Licking. Exhibit 2:(pg. no. 07-09) refers to a formulation containing Centella asiatica (Linn.) as a single ingredient used as an Intellect promoting and for the treatment of Psychosis/Insanity/Mania through oral administration. Exhibit 3:(pg. no. 10-12) refers to a formulation containing Centella asiatica (Linn.) as a single ingredient used as Memory enhancer through oral administration. Exhibit 4:(pg. no. 13-15) refers to a formulation containing Centella asiatica (Linn.) along with few other ingredients used as Strength promoting for Liver, Brain, Nerves and for the treatment of Insomnia through oral administration. Exhibit 5:(pg. no. 16-18) refers to a formulation containing Centella asiatica (Linn.) along with few other ingredients" used for the treatment of Idiopathic, psychotic syndrome, Hysteria, Psychoneurosis through oral administration. Exhibit 6:(pg. no. 19-21) refers to a formulation containing Centella asiatica (Linn.) along with few other ingredients used for the treatment of Idiopathic psychotic syndrome through oral administration. Exhibit 7:(pg. no. 22-26) refers to a formulation containing Centella asiatica (Linn.) along with few other ingredients used for the treatment of Obesity through oral administration. The alleged patent application 255/MUM/2007 claims the usefulness of a synergistic pharmaceutical composition comprising pentacyclic terpenoid glycosides, preferably asiaticoside and madecassoside optionally along with excipients, wherein pentacyclic terpenoid glycosides are obtained from plant or animal sources, preferably from the plant Centella asiatica for serotonin reuptake inhibition, wherein serotonin reuptake inhibition is useful in the management of depression, obesity, mood elevation and other disorders involving serotonin as novel. However, Centella asiatica (Linn.) has been used alone and in combination with few other ingredients as an Intellect promoting, Strength promoting for liver, Brain, Nerves and Memory enhancer and for the treatment of Psychosis/Insanity/Mania, Psychoneurosis, Hysteria, Idiopathic psychotic syndrome, Insomnia, Obesity and Neurological diseases through oral as well as local application in the Indian systems of Medicine, since long, as is evident from exhibits cited from the books namely, Khazaain- al-Advia by Mohammad Najmul Ghani Khan (Unani, Exhibit 1: pg. no. 05-06), Therayar Kappiyam by Therayar (Siddha, Exhibit 2: pg. no. 07-09), Therayar Sekarappa by Therayar (Siddha, Exhibit 3: pg. no. 10-12), Rasatantrasarah Evam Siddhaprayogasangraha (Ayurveda, Exhibit 4: pg. no. 13-15), Bhaisajya \_ Ratnavali by Govinda Dasa (Ayurveda, Exhibit 5: pg. no. 16-18), Rasakamadhenu Samhita by Cudamani(Ayurveda, Exhibit 6: pg. no. 19-21) and Bhaisajya Ratnavali by Govinda Dasa (Ayurveda, Exhibit 7: pg. no. 22-26). In addition to the aforesaid references, some other references also exist in TKDL wherein Centella asiatica has been used alone and in combination with few other ingredients for the treatment of above mentioned indications and actions. Hence the said application 255/MUM/2007 is not novel as per the cited prior art and does not involve any inventive step, therefore cannot qualify for the grant of patent rights. (For details refer exhibits filed with pregrant opposition)**

4 Subject-matter claimed in claims 1-17 involves use of the biological material for the purpose of obtaining intellectual property, therefore applicant is require to obtain necessary permission from National Biodiversity Authority as per provisions of section 6 of National Biodiversity Act 2002;

5 Subject-matter claimed in claim 1-17 uses biological materials in the form of herbal extract derived from plant material for which geographical location of the same is to be disclosed in the specification as per requirement of section 10 (4) (d) 2 (D) of Patents Act 1970;

6 Requirement of declaration made under para 9 (3) of the Form 1 of patent application is not fulfilled,

7 The proof of right is filed on 18/03/2008 which is not within the prescribed period u/r 10 of the Patent Rules, 2003. Hence cannot be taken on record.

8 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.

9 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 26/12/2014.

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.

**(A T Patre)**

Deputy Controller of Patents & Designs

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NOTE : All Communications to be sent to the Controller of Patents at INTELLECTUAL PROPERTY BUILDING S. M. Road, Antop Hill Mumbai-400 037.

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