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Date : 26/12/2013



Letter No.:-CIEM/2014/

To,
B-41, NIZAMUDDIN EAST,
NEW DELHI-110013(INDIA)

SUB : Examination Report

APPLICATION NUMBER : 1047/MUM/2008
DATE OF FILING : 15/05/2008
DATE OF REQUEST FOR EXAMINATION : 18/04/2011
DATE OF PUBLICATION : 23/07/2010

a) With reference to the RQ No. 1390/RQ-MUM/2011 Dated 18/04/2011 in the above mentioned application 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; US 5529778

D2; US6444210

D3; US6133440

D4; US6548086

D5; US6413553

D6; US6030622

Subject-matter claimed in claims 1-8 is not meeting requirement of section 2 (1) 9j) of Patents Act being obvious over document D1-D6,

Document D1 teaches an ayurvedic formulation comprising phyllanthus nirui, Tinospora cordifolia, phyllanthus emblica, Terminalia bellerica and Terminalia chebula for prophylaxis and treatment of AIDS, Flu, TB and other immune-deficiency conditions,

Document D2 discloses the effect of the bacterial polysaccharides on cell- mediated immunity in animals;

Document D3 discloses preparation and isolation of biologically active polysaccharides from Aloe as immunostimulating immunomodulating and wound healing activity,

Document D4 discloses a pharmaceutical composition comprising Cryptolepis buchanano extract for treating immunodeficiencies in animals;

Document D5 discloses the preparation of a pharmaceutical composition comprising an effective amount of lyophilized extract of piper betel and murraya koenigi as immunomodulator;

D6 discloses the preparation of a herbal extract composition comprising Arum, Pomegranate , Tea, Hibiscus for the treatment of immune disorders and HIV infection;

Further, subject-matter claimed in claims 9-14 involves process steps such as extraction of active compounds and mixing it, which is obvious to person skill in art, also the process steps does not yields technical advancement, therefore no inventive step may be acknowledged;

2 Subject-matter claimed in claims 15-16 relates to description and examples rendering the scope of the subject-matter claimed in claims indefinite, therefore does not meet requirement of section 10 (4) (c) of Patents Act.

3 **Claims 1-16 are not allowable under section 3(p) of the Act. Your attention has been drawn to the pregrant opposition filed under section 25(1) of the Act in this application. Documents & Reference 1 Vangasena: Vangasena - Commentator Shaligram Vaisya, Edited Shankar latji Jain, Khemraj Shrikrishna Das Prakashan, Bombay, Edn. 1996 Pg 388-390 Formulation ID: AK 11/ 1517 Formulation Name: Suryaprabhagutika 2.Basavaraja: Basavarajiyam-Chaukhamba Sanskrit Pratisthan, Delhi:Edn. 1st Reprint :2005 Time of origin 15th century] Pg.42 Formulation ID: AK/291 Formulation Name: Sudarsanacurnam 3.Govt of India, Sahastrayoga - Translated by D.V. Panditarao . Central Council for Research in Ayurveda & Siddha, New Delhi, 1990. [This book contains back references from 1000 B.C to 20th century] Pg.238 Formulation ID: VS/3567 Formulation Name: Madanakamesvarolehah / Caturjatarasayanam 4.V5gabhata: Astanga hirdaya - (commentary by Arunadutta) edited by Bhisagacarya Harisastri Paradakara vaidya Chaukhamba Orientalia, Varanasi, edn. 8th, 1998. [Time of origin 5th century] Pg.597 Formulation ID: RS23/464A Formulation**

Name: Vasisthaharitaki Avaleha 5.-; Bhfirata Bhaisajya Ratnakara Compiled by Naginadasa Chaganalila SSha Translated by Gopinath Gupta - Vol. -V : B. Jain Publishers, New Delhi, Edn. 2nd. Reprint, August 1 999. [This book contains back references from 1 000 B.C.to 20th century] Pg 769
Formulation ID: I-G/2 3 1/4 Formulation Name: KSme?vararasah (02) 6.Sodhala: Gadanigraha ed.Ganga Sahaya Pandeya & Com.- Indradeva Tripathi,Part-i (Prayoga Khanda) Chaukhamba Sanskrit Sansthan, Varanasi, Ed. 3rd 1 999 Pg 2 13 Formulation ID: IIG/2332 Formulation Name: Kutharakadyamurnam 7.-; Yogaratnakarah - Commentary by Laksmipatis5strl, Edited by Brahmaankara Sastri, Chaukhamba Sanskrit Sansthan (Varanasi) Ed. 7th 2002 Pg. 382 Formulation ID: BP/150 Formulation Name: Guducyadimodakah 8 I.N.A: Chimittu Rathna Churukkam. Ed: Vaidhilinga Dhesikar, Publisher: Sakalakala Nilayam Press, Chennai. (Edn: 1st 1 887) Pg 42-44 Formulation ID: GPI 3/40 Formulation Name: Kungumapoo Legyam 9.; Rasatantrasarah Evam Siddhaprayogasangraha:- part II: Krishan Gopal Ayurveda Bhawan,Edn 8th: 1990 [This book contains back references from 1000 B.C.to 20th century] Pg 72-73 Formulation ID: RS21 /69 Formulation Name: Sarvajvarahara Lauha I O.Govt of India: Sahastrayoga - Translated by D.V. Panditarao : Central Council for Research in Ayurveda & Siddha, New Delhi. 1 990. [This book contains back references from 1000 B.C.to 20th century] Pg 189 Formulation ID: VS/3437 Formulation Name: Narasiruthacurnam I 1.Abdulla Sahib: Anuboga Vaithya Navaneetham, Part - 8, Ed: Mohammad Abdullah Shahib, Publisher: Thamarai Noolagam, Chennai. (Edn: 2nd, 2002) Pg 90-92 Formulation ID: KSO 1/ 112 Formulation Name: Narasimma Ilagam I 2.Agasthiyar: Agasthiyar Vaithya Kaviyam - 1500. Ed:S.P. Ramachandran, Publisher:Thamarai Noolagam, Chennai. (Edn: 2nd, Reprint, Aug. 2001). Pg 57,58 Formulation ID: GPO 3/57 Formulation Name: Kukkil Nei-2 1 3Sodhala: Gadanigraha ed.Ganga Sahaya Pandeya & Com.- Indradeva Tripathi,Part-I (Prayoga Khanda) Chaukhamba: Sanskrit Sansthan, Varanasi, Ed. 3rd 1999 Pg 302-303 Formulation ID: AK2/487 - Formulation Name: Eladyavalcha I 4.Kannusamy Pillai : Chikithsa Rathna Deepam, Ed: C.Kannuswami Pillai, Publisher: B.Rathna Nayakar & sons, "I"hirumagal Achagam, Chennai. (Edn: 1956) Pg 175,176 Formulation ID: SK03/165 Formulation Name: Visha Raaja Pangha Thylam I 5.Govinda Dasa; Bhaisajya Ratnavali - Edited by Rajeshvaradutta Shastri, Translated by Ambikaduttashastri : Chaukhamba Sanskrit Sansthan, Varanasi, Edn. I 4th, 2001. [This book contains back references from 1 000 B.C.to 18th century] Pg 550 Formulation ID: AK/2436 Formulation Name: Mahamrtyujijayalauham I 6.Karceem Bakhsh: Miliiah-al-Khazaain (20th century AD), Dar-al- Kutub Rafecq-al- Atibba wal Ilakeem, Lahore. 1 930 AD Pg 59-60 Formulation ID: NA3/22D Formulation Name: Scemab Exhibit I:(pg. no.08-17) refers to a formulation containing Terminalia chebula Retz., Azadirachta indica A. Juss., Glycyrrhiza glabra Linn., Leptadenia reticulata Wight & Arn., Andrographis paniculata (Burm.) Nees / Swertia chirayita (Roxb. ex Flem.) Karst., Picrorhiza kurroa, Piper longum Linn., Piper nigrum Linn., Zingiber officinale Roscoe, Tinospora cordifolia Miers, Withania somnifera (Linn.) Dun. and Commiphora wightii Bhandari Syn.: C. mukul (Hook. ex Stocks) Engl. along with few other ingredients used for the treatment of Immuno suppressive / Emaciating disease, Rheumatism and Tuberculosis/Pthisis through oral administration. Exhibit 2 (pg. no.18-22) refers to a formulation containing Curcuma longa, Terminalia chebula Retz., Zingiber officinale Roscoe, Azadirachta indica A. Juss., Piper longum Linn., Glycyrrhiza glabra Linn., Holarrhena antidysenterica (Roxb. ex Flem.) Wall. ex DC., Asparagus racemosus Willd., Piper nigrum Linn., Tinospora cordifolia Miers, Picrorhiza kurroa and Swertia chirayita (Roxb. ex Flem.) Karst. along with few other ingredients used for the treatment of Influenza through oral administration. Exhibit 3:(pg. no.23-29) refers to a formulation containing Withania somnifera (Linn.) Dun., Tribulus terrestris Linn., Glycyrrhiza glabra Linn., Terminalia chebula Retz., Zingiber officinale Roscoe, Piper nigrum Linn., Piper longum Linn., Picrorhiza kurroa, Tinospora cordifolia Miers, Mucuna pruriens (Linn.) DC. Syn.: M. prurita Hook., Pueraria tuberosa DC. and Asparagus racemosus Willd. along with few other ingredients used for the treatment of Tuberculosis/Pthisis and Acute diarrhoea through oral administration. Exhibit 4:(pg. no.30-35) refers to a formulation containing Tribulus terrestris Linn., Curcuma longa, Piper longum Linn., Withania somnifera (Linn.) Dun., Mucuna pruriens (Linn.) DC. Syn.: M. prurita Hook., Tinospora cordifolia Miers, Pueraria tuberosa DC., Holarrhena antidysenterica (Roxb. ex Flem.) Wall. ex DC., Asparagus racemosus Willd., Azadirachta indica A. Juss. and Terminalia chebula Retz. along with few other ingredients used as Immuno potentiators/Anti ageing/ Anti oxidant through oral administration. Exhibit 5:(pg. no.36-40) refers to a formulation containing Withania somnifera (Linn.) Dun., Tinospora cordifolia Miers, Pueraria tuberosa DC., Tribulus terrestris Linn., Asparagus racemosus Willd., Zingiber officinale Roscoe, Piper nigrum Linn., Piper longum Linn., Mucuna pruriens (Linn.) DC. Syn.: M. prurita Hook. and Terminalia chebula Retz. along with few other ingredients used for the treatment of Immuno suppressive / Emaciating disease, Acute diarrhoea and as Immuno potentiators/Anti ageing/Anti oxidant through oral administration. Exhibit 6:(pg. no.41-45) refers to a formulation containing Ocimum sanctum Linn., Terminalia chebula Retz., Zingiber officinale Roscoe, Piper longum Linn., Piper nigrum Linn., Azadirachta indica A. Juss., Holarrhena antidysenterica (Roxb. ex Flem.) YVall. ex DC., Picrorhiza kurroa, Tinospora cordifolia Miers and Swertia chirayita (Roxb. ex Flem.) Karst. along with few other ingredients used as Immuno- potentiator / Immuno-modulator through oral administration. Exhibit 7:(pg. no.46-50) refers to a formulation containing Tinospora cordifolia Miers, Piper nigrum Linn., Piper longum Linn., Zingiber officinale Roscoe, Glycyrrhiza glabra Linn., Withania somnifera (Linn.) Dun., Asparagus racemosus Willd., Tribulus terrestris Linn. and Mucuna pruriens (Linn.) DC. Syn.: M. prurita Hook. along with few other ingredients used for the treatment of Immuno suppressive / Emaciating disease and as Immuno potentiators/Anti ageing/Anti oxidant through oral administration. Exhibit 8:(pg. no.51-58) refers to a formulation containing Tribulus terrestris Linn., Ocimum sanctum Linn., Piper longum Linn., Terminalia chebula Retz., Zingiber officinale Roscoe, Piper nigrum Linn., Glycyrrhiza glabra Linn. and Picrorhiza kurroa along with few other ingredients used for the treatment of Tuberculosis / Pthisis and Immuno-potentiator / Immuno-modulator as through oral administration. Exhibit 9:(pg. no.59-63) refers to a formulation containing Terminalia chebula Retz., Zingiber officinale Roscoe, Piper nigrum Linn., Piper longum Linn., Swertia chirayita (Roxb. ex Flem.) Karst., Picrorhiza kurroa, Glycyrrhiza glabra Linn. and Holarrhena antidysenterica (Roxb. ex Flem.) Wall. ex DC. along with few other ingredients used for the treatment of Influenza, Rheumatism and Tuberculosis / Pthisis through oral administration. Exhibit 10:(pg. no.64-67) refers to a formulation containing Asparagus racemosus Willd., Tribulus terrestris Linn., Tinospora cordifolia Miers, Zingiber officinale Roscoe, Piper nigrum Linn., Piper longum Linn. and Pueraria tuberosa DC. along with few other ingredients used for the treatment of Tuberculosis / Pthisis through oral administration. Exhibit 11:(pg. no.68-72) refers to a formulation containing Asparagus racemosus Willd., Tribulus terrestris Linn., Tinospora cordifolia Miers, Zingiber officinale Roscoe, Piper nigrum Linn., Piper longum Linn. and Glycyrrhiza glabra Linn. along with few other ingredients used for the treatment of Cancer/ Carcinoma of Penis and Vagina through oral administration. Exhibit 12:(pg. no.73-76) refers to a formulation containing Azadirachta indica A. Juss., Tinospora cordifolia Miers, Piper longum Linn., Curcuma longa, Piper nigrum Linn., Picrorhiza kurroa and Terminalia chebula Retz. along with few other ingredients used for the treatment of Cancer/ Carcinoma through oral administration. Exhibit 13:(pg. no.77-80) refers to a formulation containing Terminalia chebula Retz., Azadirachta indica A. Juss., Zingiber officinale Roscoe, Piper nigrum Linn., Piper longum Linn. and Vigna radiata (Linn.) R.Wilez. Syn.: Phaseolus radiatus Linn. along with few other ingredients used for the treatment of Tuberculosis / Pthisis and as Immuno. potentiators/Anti ageing/Anti oxidant through - oral administration. Exhibit 14:(pg. no.81-84) refers to a formulation containing Terminalia chebula Retz., Andrographis paniculata (Burm.) Nees / Swertia chirayita (Roxb. ex Flem.) Karst., Tinospora cordifolia Miers, Azadirachta indica A. Juss. and Piper nigrum Linn. along with few other ingredients used for the treatment of Cancer/ Carcinoma through oral administration. Exhibit 15:(pg. no.85-90) refers to a formulation containing Picrorhiza kurroa, Curcuma longa, Holarrhena antidysenterica (Roxb. ex Flem.) Wall. ex DC., Terminalia chebula Retz., Zingiber officinale Roscoe and Tinospora cordifolia Miers along with few other ingredients used for the treatment of Cirrhosis of liver through oral administration. Exhibit 16:(pg. no.91-93) refers to a formulation containing Caesalpinia bonducella Flem. as a single ingredient used for the treatment of Dysenteric diarrhoea/Haemorrhagic diarrhoea through oral administration. The alleged patent application 1047/MUM/2008 claims the usefulness of an immunomodulator herbal formulation comprising an extract of at least one plant selected from Cressa eretica, Leptadenia reticulata, Tinospora cordifolia, Picrorhiza kurroa, Chlorophytum borivillianum, Zingiber officinale, Tribulus terrestris, Caesalpinia bondoc, Asparagus racemosus, Piper longum, Swertia chiraita, Phaeocolus radiatus, Piper nigrum, Withania somnifera, Ocimum sanctum, Mucuna pruriens, Commiphora wightii, Glycyrrhiza glabra, Holarrhena antidysenterica, Pueraria tuberosa, Curcuma longa,

Azadirachta indica, Terminalia chebula or a combination thereof for the treatment of Acquired Immune Deficiency Syndrome, flu, tuberculosis, hepatitis, cirrhosis, diarrhoea, cancer and immunodeficiency conditions. However Terminalia chebula Retz., Azadirachta indica A. Juss., Glycyrrhiza glabra Linn., Leptadenia reticulata Wight & Arn., Swertia chirayita (Roxb. ex Flem.) Karst., Picrorhiza kurroa, Piper longum Linn., Piper nigrum Linn., Zingiber officinale Roscoe, Tinospora cordifolia Miers, Commiphora wightii Bhandari Syn.: C. mukul (Hook. ex Stocks) Engl., Curcuma longa, Holarrhena antidysenterica (Roxb. ex Flem.) Wall. ex DC., Asparagus racemosus Willd., Withania somnifera (Linn.) Dun., Tribulus terrestris Linn., Mucuna pruriens (Linn.) DC. Syn.: M. prurita Hook., Ocimum sanctum Linn., Pueraria tuberosa DC., Phaseolus radiatus Linn. and Caesalpinia bonducella Flem. has been used for the treatment of Immuno suppressive / Emaciating disease, Rheumatism, Cancer/ Carcinoma, Tuberculosis/Phtysis, Influenza, Acute diarrhoea, Cirrhosis of liver, Dysenteric diarrhoea/ Haemorrhagic diarrhoea, Cancer/ Carcinoma of Penis and Vagina and as Immuno potentiators/Anti ageing/Anti oxidant and Immuno-potentiator / Immuno-modulator through oral administration, in the Indian system of medicine, since long, as is evident from exhibits cited from the books namely Vangasena by Vangasena(Ayurveda, Exhibit 1: pg. no.08-17), Basavarajiyam by Basavaraja(Ayurveda, Exhibit 2: pg. no.18-22), Sahastrayoga by Govt of India(Ayurveda, Exhibit 3: pg. no.23-29), Astanga Hrdaya by Vagabhata (Ayurveda, Exhibit 4: pg. no.30-35), Bharata Bhaisajya Ratnakara(Ayurveda, Exhibit 5: pg. no.36-40), Gadanigraha by Sodhala(Ayurveda, Exhibit 6: pg. no.41-45), Yogaratnakarah(Ayurveda, Exhibit 7: pg. no.46-50), Chimitu Rathna Churukkam by I.N.A(Siddha, Exhibit 8: pg. no.51-58), Rasatantrasarah Evam Siddhaprayogasamgrahah(Ayurveda, Exhibit 9: pg. no.59-63), Sahastrayoga by Govt of India(Ayurveda, Exhibit 10- pg. no.64-6.7), Anuboga Vaithya Navaneetham, Part - 8 by Abdulla Sahib(Siddha, Exhibit 11: pg. no.68-72), Agathiyar Vaithya Kaviyam - 1500 by Agathiyar(Siddha, Exhibit. 12: pg. no.73-76), Gadanigraha by Sodhala(Ayurveda, Exhibit 13: pg. no.77-80), Chikitsa Rathna Deepam by Kannusamy Pillai(Siddha, Exhibit 14: pg. no.81-84), Bhaisajya Ratnavali by Govinda Dasa(Ayurveda, Exhibit 15: pg. no:85-90) and Miftaah- al- Khazaain by Kareem Bakhsh(Unani, Exhibit 16: pg. no.91-93). In addition to the -aforesaid references, some other references also exist in TKDL, wherein the above mentioned plants have been used alone or along with few other ingredients for the treatment of Immuno suppressive / Emaciating disease, Rheumatism, Cancer/ Carcinoma, Tuberculosis/Phtysis, Influenza, - Acute diarrhoea, Cirrhosis of liver, Dysenteric diarrhoea/ Haemorrhagic diarrhoea, Cancer/ Carcinoma of Penis and Vagina and as Immuno potentiators/Anti ageing/Anti oxidant and Immuno-potentiator / Immuno-modulator through oral administration. (For details refer exhibits filed with pregrant opposition)

4 Subject-matter claimed in claims 1-16 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 1-16 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 Subject-matter claimed in claims 1-16 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;

7 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

8 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 FIR 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

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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