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Letter No.:-BIO-TECH/2013/

Date : 08/10/2013

To,
SOUMILI DAS
K & S PARTNERS,
INTELLECTUAL PROPERTY ATTORNEYS
84-C, C-6 LANE, (OFF CENTRAL AVENUE)
SAINIK FARMS, NEW DELHI ? 110 062, INDIA.

SUB : Examination Report

APPLICATION NUMBER : 2645/del/2005
DATE OF FILING : 04/10/2005
DATE OF REQUEST FOR EXAMINATION : 05/10/2009
DATE OF PUBLICATION : 02/10/2009

With reference to the RQ No. 8048/RQ-DEL/2009 Dated 05/10/2009 in the above mentioned application for Grant
a) of Patent , Examination has been conducted under Section 12 and 13 of the Patents Act 1970 . The following objections are hereby communicated

b) **Objections :**

Subject matter of the claimed invention lacks novelty and inventive step u/s 2(1(j)) of the Patents Act, 1970 in view of below cited documents from TKDI, and documents cited in the pre grant opposition filed by TKDI.(copy attached):

AK15/200A Madhumeha Vinasini Vatika (svarna Yukta)

Useful in the Treatment of following Diseases : Diabetes mellitus(madhumeha),

IPC Codes : A61K 33/00, A61K 35/04, A61K 36/00, A61K 36/27, A61K 36/47, A61K 36/58, A61K 36/9066, A61K 9/08, A61K 9/14, A61K 9/20, A61P 3/10, A61P 5/00, A61P 5/48, C01B 5/00, C01G 19/00, C01G 21/00, C01G 7/00, C01G 9/00

Knowledge Known Since : 50 years

Bibliography : Ras?m?tam .

Keyword(s)/Ingredient(s) : Lead(n?ga) , Tin / Stannum(va?ga) ,Zinc(ya?ada) ,Gymnema sylvestre (Retz.) R.Br. ex Schult.(me?a???g?, madhun??in?) Leaf(patra),Azadirachta indica A. Juss.(nimba) Leaf(patra),A gummy exudate collected from rocks(?il?]?ta/?il?]?jatu) .Gold(svar?a)

D2:RS21/442 Sresthadi Vati

Useful in the Treatment of following Diseases : Pittaja(pittaja),Kaphaja(kaphaja),Urinary disorders / Polyuria(Prameha / meha),Diabetes mellitus(madhumeha),Diabetic furuncle(prameha pi?ik?).

IPC Codes : A61K 125/00, A61K 129/00, A61K 131/00, A61K 33/00, A61K 36/00, A61K 36/27, A61K 36/328, A61K 36/47, A61K 36/54, A61K 36/58, A61K 36/60, A61K 36/9066, A61K 9/08, A61K 9/20, A61P 13/00, A61P 13/02, A61P 17/02, A61P 29/00, A61P 3/10, A61P 31/00, A61P 31/02, A61P 5/00, A61P 5/48, A61P 5/50, A61P 7/12, C01B 17/00, C01G 19/00

Knowledge Known Since : 50 years

Bibliography : Rasatantras?ra? Evam Siddhaprayogasa?graha?..

Keyword(s)/Ingredient(s) : triphal?, Terminalia chebula Retz.(har?tak?), Terminalia bellirica (Gaertn.) Roxb.(bibh?taka), Phyllanthus emblica Linn. Syn.: Emblica officinalis Gaertn.(?malak?), Sulphur(Gandhaka) Purified (?uddha), Curcuma longa(haridr?) Rhizome(prakanda), Gymnema sylvestre (Retz.) R.Br. ex Schult.(me?a???g?, madhun??in?) Leaf(patra), Cinnamomum camphora (Linn.) J. Presl(karp?ra), Tin / Stannum(va?ga) Calcined / Incinerated drug(Bhasma), Azadirachta indica A. Juss.(nimba) Stem bark(k?n?atvak), Commiphora wightii Bhandari Syn.: C. mukul (Hook. ex Stocks) Engl.(guggulu) Exudate(niry?sa), Phyllanthus emblica Linn. Syn.: Emblica officinalis Gaertn.(?malak?) Fruit(phala), Gymnema sylvestre (Retz.) R.Br. ex Schult.(me?a???g?, madhun??in?) Leaf(patra), Ficus racemosa Linn.(udumbara) Stem bark(k?n?atvak), Gymnema sylvestre (Retz.) R.Br. ex Schult. (me?a???g?, madhun??in?) Leaf(patra)

D3:RG12/814B Candraprabha Vati Anupana Evam Upayoga

Useful in the Treatment of following Diseases : Urinary disorders / Polyuria(Prameha / meha), Polyuria / Diabetes insipidus (udakameha), Diabetes mellitus(madhumeha), Oedema / Inflammation(?otha),

IPC Codes : A61K 131/00, A61K 135/00, A61K 35/20, A61K 36/00, A61K 36/185, A61K 36/29, A61K 36/59, A61K 36/75, A61K 9/08, A61K 9/20, A61P 1/10, A61P 13/00, A61P 13/02, A61P 13/04, A61P Knowledge Known Since : 50 years

Bibliography : ?yurveda S?rasa?graha? ,

Keyword(s)/Ingredient(s) : Freshly milked milk(Dharosna dugdha), Tinospora cordifolia Miers(gu??e?) Stem(k???a), Berberis aristata DC. / Berberis asiatica Roxb. / Berberis lycium Royle(d?ruharidr?) Stem(k???a), Aegle marmelos Correa ex Roxb.(bilva) Leaf(patra), Tribulus terrestris Linn.(gok?ura) Fruit(phala), Honey(madhu/k?audra)

D4:Sl. 1/413 Madhumehari Yoga

Useful in the Treatment of following Diseases : Burning sensation in palms and soles(hasta pada daha), Pyrexia(jvara), Polyuria / Diabetes insipidus(udakameha), Urinary disorders / Polyuria(Prameha / meha), Dryness of mouth(mukha?o?a), Polydipsia / Excessive thirst(t????), Diabetes mellitus(madhumeha),

IPC Codes : A61K 125/00, A61K 131/00, A61K 135/00, A61K 35/04, A61K 36/00, A61K 36/185, A61K 36/27, A61K 36/42, A61K 36/48, Knowledge Known Since : 0 years

Bibliography : Siddhaprayogalatika

Keyword(s)/Ingredient(s) : Momordica charantia Linn.(k?ravellik?) Fruit(phala), Pterocarpus marsupium Roxb.(b?jaka (asana)) Heart wood(k???hamajj?), Syzygium cuminii (Linn.) Skeels(jamb?) Seed(b?ja/ phal?sthi), Azadirachta indica A. Juss.(Nimba) Leaf(patra), Swertia chirayita (Roxb. ex Flem.) Karst.(kir?tatikta) St.Bark, Leaf, Flower, Fruit & Root(Pancanga), Pierorhiza kurroa(ka?uk?, ku?ak?) Rhizome(prakanda), Calotropis gigantea (Linn.) Ait. f.(alarka (?veta)) Root(m?la), Salacia chinensis Linn. Syn. S.latifolia Wall. ex M. Laws., S.prinoides DC (saptara?g?, saptacakr?), Trigonella foenum-graecum Linn.(meth?) Seed(b?ja/ phal?sthi), Cinnamomum tamala Nees(tejapatra, nalik? (sth?n?panna au?adhi)) Leaf(patra), A gummy exudate collected from rocks(?il?j?ta/?il?jatu) Purified(?uddha), Curcuma longa(haridr?) Rhizome(prakanda), Gymnema sylvestre (Retz.) R.Br. ex Schult.(me?a???g?, madhun??in?) Leaf(patra), Sesamum indicum Linn.(tila) Seed(b?ja/ phal?sthi), Papaver somniferum Linn.(ahiphena) Fruit exudate(phalaniry?sa), cow urine(gaumutra), Azadirachta indica A. Juss.(Nimba) Leaf(patra).

D5:GP04/82 Kodaga Sala Kuligai

Useful in the Treatment of following Diseases : Vataja(Vali, Vaatham, Vaayu), Cancer/ Carcinoma(Putru noi, Vipuruthi), Ascites(Peruvayiru), Ozaena, sinusitis(HR)(Neer Kovai), Retention of urine(Neer kattu), Syncope/Fainting(Mayakka noi, Sanniyaasam), Pain(Vali), Incurable(Theeraa Noigal), Ulcer / Wound

Healing(Pun), Ascites(Peruvayiru), Diabetes mellitus(Inippuneer/Neerazhivu), Disease(Noi, Vyaadhi, Pini), Ulcer / Wound Healing(Pun), Acne vulgaris(Muga paru), Pain(Vali), Diseases of the eye(Kan Noigal),

IPC Codes : A61K 131/00, A61K 35/20, A61K 35/22, A61K 35/24, A61K 35/413, A61K 36/00, A61K 36/185, A61K 36/19, A61K 36/42, A61K 36/47, A61K 36/53, A61K 36/67, A61K 36/725, A61K 36/75, Knowledge Known Since : 500 years

Bibliography : Therayar Maha Karisal.

Keyword(s)/Ingredient(s) : Bovine gall stone / Bezoar(Gorojanam,Myrosanam,Vathsala mani,Rosanam,Komandhiram) .Zingiber officinale Roscoe(Inji, chukku) Rhizome(Ver Kombu,Matta nila thandu),Piper nigrum Linn.(Milagu) Fruit(Pazham),Piper longum Linn.(Thippili, Pippili) Fruit(Pazham),Terminalia chebula Retz.(Kadukkaai) Unripe fruit(Pazhakkaai),Phyllanthus emblica Linn. Syn.: Emblica officinalis Gaertn. (Nelli) Unripe fruit(Pazhakkaai),Terminalia bellirica (Gaertn.) Roxb.(Thaandri) Unripe fruit(Pazhakkaai),Costus speciosus (Koen. ex Retz.) Smith(Koshtam, Kura, Oli, Kuravam) Rhizome(Ver Kombu,Matta nila thandu),Orpiment / Arsenic trisulphide(Thalakam,ArIthaaram,Ponvarni,Maaldevi,Kothandham,Pecthagi,Aalambi,Kaal puthi,Paluppu,Manjal varni) ,Coral / Corallium rubrum(Pavazham,Pravaalam,Thukir,Thuppu,Vaarithi thandu,Senthandu maalai) ,Coccinia grandis (Linn.) Voigt Syn.: C. indica Wight & Arn. (Kovai, Kuwai) Root(Ver),Molineria finlaysoniana Bak.(Nilapanai) Root(Ver),Zizyphus mauritiana Lam.(Ilandhai, Aditharam, Iradi, Koli, Kullari, Sivagam, Veyam, Padari) Root(Ver),Leucas aspera Spreng.(Thumbai,Imuganaar vettri) Root(Ver), Root(Ver),Cannabis sativa Linn.(Kanja,Korakkar mooli,Siva mooli,Karpa mooli,Moodandam,Bangi,Madamathakam) Root(Ver),Cow(Pasu,Komaadhaa) ,Hoepa glabra Wight & Arn.(Kongu) Leaf(Ilai,Thazhai),Indoneesiella echioides (Linn.) Sreen. Syn. Andrographis echioides (Linn.)

D6:AK/2328 Triphal?dyamlauham

Useful in the Treatment of following Diseases : Obesity (medov?ddhi),Lethargy(a?gas?da),Itching(ka??),Disease with Kapha predominance(kaphavik?ra),

IPC Codes : A61K 125/00, A61K 129/00, A61K 131/00, A61K 135/00, A61K 31/00, A61K 36/00, A61K Knowledge Known Since : 200 years

Bibliography : Bh?rata Bhai?ajya Ratn?kara ,Cakradatta? ,Gadanigraha? ,Bhai?ajya Ratn?val? ,V?ndam?dhava,

Keyword(s)/Ingredient(s) : triphal?,Terminalia chebula Retz.(har?tak?),Terminalia bellirica (Gaertn.) Roxb.(bibh?taka),Phyllanthus emblica Linn. Syn.: Emblica officinalis Gaertn.(?malak?),Sesamum indicum Linn.(tila) Oil(taila),Ammi visnaga (Linn.) Lam. (p????abhed?) Rhizome(prakanda),Marsdenia tenacissima Wight. & Arn. / Chonemorpha fragrans (Moon) Alston Syn. C. macrophylla (Roxb.) G. Don. (m?rv?) Root(m?la), Root(m?la),Plumbago zeylanica Linn.(citraka) Root(m?la),Justicia adhatoda Linn. Syn.: Adhatoda vasica Nees(v?s?) Leaf(patra),Azadirachta indica A. Juss.(nimba) Stem bark(k?n?atvak),Cassia fistula Linn.(?ragvadha) Fruit(phala),Acorus calamus Linn.(vac?) Root(m?la),Alstonia scholaris (Linn.)R. Br.(saptapar?a) Stem bark(k?n?atvak),Curcuma longa(haridr?) Rhizome(prakanda),Berberis aristata DC. / Berberis asiatica Roxb. / Berberis lycium Royle(d?ruharidr?) Root(m?la),Tinospora cordifolia Miers(gu??e?) Stem(k??a),Vitex negundo Linn.(nirgu???, re?uk? bheda) Leaf(patra), Fruit(phala),Saussurea lappa Clarke(ku??ha) Root(m?la),Brassica rapa Linn. Syn.: B. campestris Linn.(sar?apa) Seed(b?ja/ phal?sthi),Zingiber officinale Roscoe(?rdraka, ?u??h?) Rhizome(prakanda), Water(jala/udaka).

D7:PD04/54 Amukkara Karpam

Useful in the Treatment of following Diseases : Obesity (Udal Paruman,Athi thoola noi),Anaemia / Hyperbilirubinaemia (Vellupponoi,Paandu,Ratha kuraivu),Rat bite poisoning(Flikkadi Nanju),Snake bite(Paampukkadi),Scabies, Itch(Sori sirangu),Emaciation / Cachexia(Udal Ilaippu Noi),Pain(Vali),Gastric ulcer/Acute gastritis(Gunmam/Iraippai Soolai , Aamasoolai),Hyperemesis gravidarum(Sool Vaanthi,Masakkai,Sool vida vaanthi),Leprosy(Thozhunoi, Kuttam,

Perunoi),Vataja(Vali,Vaatham,Vaayu),Disease(Noi,Viyaadhi,Pini),Gaseous/Flatulence(Vaayu),Amenorrhoea(Soothaga Thadai),Delirium(Sanni Noi),Carbuncle/Furuncle(Pilavai, Vipuruthi, Pudai),Oedema /

Inflammation(Veekkam).Diseases of Infants and Children (Kuzhavi/ Kuzhanthai Noigal),Whooping cough(Kakkuvaan Erumal),Jaundice(Manjal noi ,kamalai,Pithu noi),

IPC Codes : A23C 15/00, A61K 129/00, A61K 131/00, A61K 35/20, A61K 35/22, A61K 36/00, A61K Knowledge Known Since : 1000 years

Bibliography : Agathiar vaithiam 600,

Keyword(s)/Ingredient(s) : Withania somnifera (Linn.) Dun.(Nattuamukira Irulichevi, Kidichevi, nagudaver, Varagakarni, Asubam, Amukkara) St.Bark,Leaf,Flower,Fruit&Root(Samoolam

Claims of the present invention are related to Aacomposition useful in the treatment of diabetic complications. said composition comprising herbs selected from Curcuma longa, Berberis aristata, Tinospora cordifolia, Andrographis paniculata, Azadirachta indica, Gymnema sylvestre, Momordica charantia, Asphaltum (Mineral Origin), and optionally Terminalia chebula, Terminalia bellirica, Emblica officinalis, Vetiveria Zizanoides, Withania somnifera, Strychnos Potatorum, Zinziber officinale, Piper longum, Ocimum sanctum and Bacopa monieri together with acceptable excipients.

The said ingredients are already known traditionally for their use in treatment od diabetic complications either alone

or in combination. There are lot of documents in TKDL related to the use of ingredients claimed in the composition for the diabetes treatment. Thus in view of known use of these ingredients either alone or in combination for pm claims 1-8 of the present application lacks novelty and inventive step.

2 **Claims 1-8 falls under section 3(p) of the Patents Act, 1970 as medicinal property of all the extracts and the minerals given the composition claim are known in traditional knowledge. The invention as claimed is traditional knowledge and aggregation or duplication of known properties of traditionally known components.**

Claims 1-8 fall u/s 3(e) of the Patents (Amended) Act, 2005 as the said claims defines a mere admixture resulting only in the aggregation of the properties of the components thereof. It is not clear if the combined agents act together to provide a technical effect that is greater than just the sum of the two or more agents alone, or whether the combination is in fact a mere juxtaposition with no interaction of the agents.

3 The composition should be synergistic and should shows unexpectedly new property or better efficacy than a mere aggregation of the properties of its components. To establish such synergism experimentation with the composition and their working examples are essential. The specification doesn't provide any such support. The specification doesn't cover the whole scope of the claimed invention and the invention can't be carried out without undue experimentation. Hence the main claim lacks support and the application lacks disclosure.

4 Claims fall u/s 3(d) of the Patents (Amended) Act, 2005 as the said claims defines new use and/or new form of the known compounds (as cited by the prior art documents as described in para 1 of the report). In the absence of experimental data, it is not clear if the said composition act to provide an enhancement of the known efficacy i.e., demonstrate a greater technical effect and/or differ significantly in properties w.r.t the known compounds.

Claim-1 is not definitive and do not sufficiently define the invention. Claim should clearly define all ingredients with their percentage/ratio.

5 Claim-4 attracts section 3(i) as it talks about dosage form which is not patentable subject matter.

Claim-5 and 6 are vaguely defined in view of expression health food, effective amount. Claim is very vaguely defined.

1) Declaration by the applicant should be made in Para 9(iii) of Form 1, regarding necessary permission from the competent authority for using biological material from India according to the second schedule of the Patents Rule, 2003.

6 **2) 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 Authority, relevant application form (Form 3 , Rule !8) for such permission is available in website of national Biodiversity Authority.**

3) Source /geographical origin of the biological materials used in the specification should be provided in the specification in accordance to section 10(4)(ii)(D).. The required permission from the NBA should be provided.

7 Power of Authority with prescribed stamped duty and the particulars of the case should be filed.

8 Abstract should be filed as per rule 13(7)(a) of the Patent Rules, 2003

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 sction 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
c) within 12 months 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 08/10/2014.

- 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.

(Dr. N. Mukherj

Asst. Controller of Patents & Desi

**NOTE ; All Communications to be sent to the Controller of Patents at INTELLECTUAL PROPERTY BUILDING
Plot No. 32, Sector-14,Dwarka New Delhi - 110 078.**

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