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Letter No.:-BIO-TECH/2013/

Date : 08/04/2013

To,
65-C, POCKET J & K,
DILSHAD GARDEN, DELHI-110095, INDIA.

SUB : Examination Report

APPLICATION NUMBER : 1065/DEL/2009
DATE OF FILING : 25/05/2009
DATE OF REQUEST FOR EXAMINATION : 25/05/2009
DATE OF PUBLICATION : 25/12/2009

With reference to the RQ No. 4230/RQ-DEL/2009 Dated 25/05/2009 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 :**

1065/del/2009

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 and documents cited in the pre grant opposition :

DI:AT/237 Pa?canimbac?r?a

Useful in the Treatment of following Diseases : All types(sarvaprak?rake),Leprosy and other dermatoses(ku??ha).

IPC Codes : A61K 125/00, A61K 129/00, A61K 131/00, A61K 31/70, A61K 33/00, A61K 35/20, A61K

Knowledge Known Since : 500 years

1 **Bibliography :** Rasayoga S?gara ,??r?gadhara Sa?hit? ,

Keyword(s)/Ingredient(s) : Azadirachta indica A. Juss.(nimba) Leaf(patra),Azadirachta indica A. Juss.(nimba) Root(m?la),Azadirachta indica A. Juss.(nimba) Stem bark(k?n?atvak),Azadirachta indica A. Juss.(nimba) Fruit(phala),Iron(lauha) Calcined / Incinerated drug(Bhasma),Terminalia chebula Retz.(har?tak?) Fruit(phala),Cassia tora Linn.(prapunn??a, cakramarda) Seed(b?ja/ phal?sthi),Plumbago zeylanica Linn.(citraka) Root bark(m?latvak),,Embelia ribes Burm. f. / Embelia tsjeriam-cottam A. De Syn. E. robusta C.B Clarke(vi?a?ga) Fruit(phala),Granular sugar(?arkar?) ,Phyllanthus emblica Linn. Syn.: Emblica officinalis Gaertn.(?malak?) Fruit(phala),Curcuma longa(haridr?) Rhizome(prakanda),Piper longum Linn.(pippal?) Fruit(phala),Piper nigrum Linn.(marica) Fruit(phala),Zingiber officinale Roseoe(?rdraka, ?u??h?) Rhizome(prakanda),Psoralea corylifolia Linn.(b?kuc?) Seed(b?ja/

phal?sthi), Cassia fistula Linn. (?ragvadha) Fruit pulp (phalamajj?), Tribulus terrestris Linn. (gok?ura)
Fruit (phala)

D2: AB/1065 Khadir?digu?ik? (06) (see annexure D2)

Useful in the Treatment of following Diseases : Leprosy and other dermatoses (ku??ha),

Knowledge Known Since : 500 years

Bibliography : Bh?rata Bhai?ajya Ratn?kara, Gadanigraha?,

Keyword(s)/Ingredient(s) : triphal?, Terminalia chebula Retz. (har?tak?), Terminalia bellirica (Gaertn.) Roxb. (bibh?taka), Phyllanthus emblica Linn. Syn.: Emblica officinalis Gaertn. (?malak?), Acacia catechu (Linn. f.) Willd. (khadira) Heart wood (k???hamajj?), Pterocarpus marsupium Roxb. (b?jaka (asana)) Heart wood (k???hamajj?), Azadirachta indica A. Juss. (nimba) Stem bark (k?n?atvak), Holarrhena antidysenterica (Roxb. ex Flem.) Wall. ex DC. (ku?aja, indrayava) Stem bark (k?n?atvak), Urine (m?tra) Cow (gau), Water (jala/udaka), Semecarpus anacardium Linn. f. (bhall?taka) Fruit (phala), Embelia ribes Burm. f. / Embelia tsjeriam-cottam A. Dc Syn. E. robusta C.B Clarke (vi?a?ga) Fruit (phala), Acorus calamus Linn. (vac?) Rhizome (prakanda), Plumbago zeylanica Linn. (citraka) Root (m?la), Psoralea corylifolia Linn. (b?kuc?) Seed (b?ja/ phal?sthi), Solanum nigrum Linn. (k?kam?c?) Root (m?la),

D3: AB/741 K?ka?aghnava?? (see annexure D3)

Useful in the Treatment of following Diseases : Leprosy and other dermatoses (ku??ha),

Knowledge Known Since : 200 years

Bibliography : Bh?rata Bhai?ajya Ratn?kara ,

Keyword(s)/Ingredient(s) : triphal?, Terminalia chebula Retz. (har?tak?), Terminalia bellirica (Gaertn.) Roxb. (bibh?taka), Phyllanthus emblica Linn. Syn.: Emblica officinalis Gaertn. (?malak?), Iron (lauha) Calcined / Incinerated drug (Bhasma), Aconitum ferox Wall. ex Ser. (vatsan?bha bheda) Root tuber (m?lakanda), Plumbago zeylanica Linn. (citraka) Root (m?la), Picrorhiza kurroa (ka?uk?, ku?ak?) Root (m?la), Plumbago zeylanica Linn. (citraka) Root (m?la), Cyperus rotundus Linn. / Cyperus scariosus R. Br. / Cyperus arundinaceum Baker (mustaka, ga??ad?rv?) Rhizome (prakanda), Embelia ribes Burm. f. / Embelia tsjeriam-cottam A. Dc Syn. E. robusta C.B Clarke (vi?a?ga) Fruit (phala), Terminalia chebula Retz. (har?tak?) Fruit (phala), Azadirachta indica A. Juss. (nimba) Stem bark (k?n?atvak), Embelia ribes Burm. f. / Embelia tsjeriam-cottam A. Dc Syn. E. robusta C.B Clarke (vi?a?ga) Fruit (phala), Acacia catechu (Linn. f.) Willd. (khadira) Stem bark (k?n?atvak), Justicia adhatoda Linn. Syn.: Adhatoda vasica Nees (v?s?) Leaf (patra), Tinospora cordifolia Miers (gu??c?) Stem (k???a),

D4: AK10/615 Kustaghna Mahakasaya (see annexure D4)

Useful in the Treatment of following Diseases : Leprosy and other dermatoses (ku??ha),

D5: AK11/2537 Manjisthadi Mahakasaya (see annexure D5)

Useful in the Treatment of following Diseases : Diseases due to vitiated blood (Raktaja roga / Rakta vikara), Itching (ka???), Eruptions (vispho?aka), Intestinal obstruction due to indigestion (alaska), Psoriasis (ki?ibha), Leucoderma/Vitiligo (??vitra), Eczema (p?m?),

D6: VS/862 Rasendrama?galarasa? (see annexure D6)

Useful in the Treatment of following Diseases : Lepromatous leprosy (pu??ar?kaku??ha), All types (sarvaprak?rake), Leprosy and other dermatoses (ku??ha),

D7: AK/2991 Mah?t??akatailam (cakradatta?)

Useful in the Treatment of following Diseases : All types (sarvaprak?rake), Diseases of skin (carmaroga),

IPC Codes : A61K 125/00, A61K 129/00, A61K 131/00, A61K 133/00, A61K 135/00, A61K 31/00, A61K **Knowledge Known Since :** 500 years

Bibliography : Cakradatta?, Bhai?ajya Ratn?val?,

Keyword(s)/Ingredient(s) : triphal?, Terminalia chebula Retz. (har?tak?), Terminalia bellirica (Gaertn.) Roxb. (bibh?taka), Phyllanthus emblica Linn. Syn.: Emblica officinalis Gaertn. (?malak?) Plumbago zeylanica Linn. (citraka), Alstonia scholaris (Linn.) R. Br. (saptapar?a), Stem bark (k?n?atvak), Azadirachta indica A. Juss. (nimba), Psoralea corylifolia Linn. (b?kuc?) and other ingredients.

There are a lot of references in the TKDL which indicates the use of Azadirachta Indica (Neem) Oil, Mustard Oil, Plumbago Rosea / Plumbago Zeylanaca, Psoralea Corylifolia, Terminalia Chebula and Embelia Ribes alone or in composition form in the treatment of various types of skin diseases such as fungal skin infection, bacterial skin infections, virus skin infections like eczema, psoriasis, scabies, allergies etc. In view of known uses of the plants it is obvious for a person skilled in the art to combine them in the given ratios and claim for the known uses. In view of above discussed prior art and the prior art cited in the pre grant opposition claims 1-4 of the present application lacks inventive step. Claims should clearly provide the novel and inventive features over the above discussed prior art.

2 Claims 1-4 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.

3 Claims- 1-3 falls u/s 3(e) of the Patents act, 1970 as the composition and the process claimed is a mere admixture of known ingredients 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. Percentage/ratio of ingredients should be provided with synergistic effect and synergistic effect should be shown with the help of supporting examples.

4 Claims 1-4 falls under section 3(p) of the Patents Act, 1970 as medicinal property of all the plants 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.

1) 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).

5 2) 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.

3) 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.

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

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 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 08/04/2014.

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. Mukherjee)

Asst. Controller of Patents & Designs

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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