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Letter No.: -BIO-TECH/2013/

Date : 11/06/2013

To,  
BHUPATHIRAJU VSSRK RAJU  
Fox Mandal Little  
FM House, Sector-9,  
Noida - 201301 NCR OF Delhi

SUB : **Examination Report**

APPLICATION NUMBER : 1212/DEL/2009  
DATE OF FILING : 12/06/2009  
DATE OF REQUEST FOR EXAMINATION : 06/08/2009  
DATE OF PUBLICATION : 01/01/2010

With reference to the RQ No. 6446/RQ-DEL/2009 Dated 06/08/2009 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 :**

1212/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 (attached along with):

(Source TKDL)D1:RG9/298 Katuka Guna (see annexure)

Useful in the Treatment of following Diseases : Ring worm (dadru), Diseases of skin (carmaroga), Diseases of heart(h?dayaroga), Diseases of spleen(p?h?vik?ra), Disease(roga/ vy?dhi),

IPC Codes : A61K 125/00, A61K 36/80, A61P 1/04, A61P 1/06, A61P 1/08, A61P 17/00, A61P 17/02, A61P 17/04,

Knowledge Known Since : 500 years

Bibliography : So?halanigha??au?,

Keyword(s)/Ingredient(s) : Pierorhiza kurroa(ka?uk?, ku?ak?) Rhizome(prakanda),

D2:MH5/3106B Marham Aswad Deegar (see annexure)

Useful in the Treatment of following Diseases : Wound(Zakhm/Jaraahat), Piles / Ano rectal mass / Haemorrhoids(Bawaaseer), Anal Fissure(Shiqaaq -e- Maq"ad), Scabies, Itch(Jarab-wa-Hikka), Alopecia (Daa-al-Sa?lab), Septic wounds(Jurooh-e-Muta?fiyah),

IPC Codes : A61J 3/00, A61J 3/04, A61K 31/04, A61K 31/05, A61K 36/63, A61K 36/9066, A61K 9/08,

Knowledge Known Since : 500 years

Bibliography : Quaraabaadeen Quaadri,

Keyword(s)/Ingredient(s) : Massicot/Lead oxide/Plumbi oxidum(Murdaar Sang) ,Olea europaea Linn.(Zaitoon) Oil(Roghan),Alcoholic drink(Sharaab) ,Curcuma longa(Zard Chob/Haldi/ Urooq al Sufri/ Urooq al Zafraan) ,

D3:NA4/2331 Raughan Daa-al-saalab (see annexure D3)

Useful in the Treatment of following Diseases : Alopecia (Daa-al-Sa?lab),

D4:MA2/222 Nuskha-e-tila

Useful in the Treatment of following Diseases : Alopecia (Daa-al-Sa?lab),Alopecia Furfuracea(Daa-al-Hayyah),

IPC Codes : A61K 125/00, A61K 31/10, A61K 36/00, A61K 36/185, A61K 36/58, A61K 36/76, A61P 17/00, A61P 17/14

Knowledge Known Since : 1000 years

Bibliography : Kitaab al U"mdah fil Jeraahat ,

Keyword(s)/Ingredient(s) : Salix caprea Linn.(Bed Mushk) Leaf(Barg/Patti),Sesamum indicum

Linn.(Kunjad Siyah/Til/Sheeraj) Leaf(Barg/Patti),Azadirachta indica A. Juss.(Neem)

Leaf(Barg/Patti),Sesamum indicum Linn.(Kunjad Siyah/Til/Sheeraj) Root(Beekh/Asl/Usool),

D5:AK10/639 Brihanamajistadi Kvatha

Useful in the Treatment of following Diseases : Diseases of skin (carmaroga),All

types(sarvaprak?rake),Leprosy and other dermatoses(ku??ha),Gout

(v?tarakta),Paraesthesia(prasupti),Erysipelas(visarpa),Abscess (vidradhi),Diseases due to vitiated blood(Raktaja roga / Rakta vikara).

IPC Codes : A61K 125/00, A61K 129/00, A61K 131/00, A61K 135/00, A61K 36/00, A61K 36/15, A61K /00

Knowledge Known Since : 200 years

Bibliography : Yogatrangini ,

Keyword(s)/Ingredient(s) : triphal?,Terminalia chebula Retz.(har?tak?),Terminalia bellirica (Gaertn.)

Roxb.(bibh?taka),Rubia cordifolia Linn.(ma?ji??h?) Stem(k??a),Curcuma longa(haridr?)

Rhizome(prakanda),Berberis aristata DC. / Berberis asiatica Roxb. / Berberis lycium Royle(d?ruharidr?)

Stem(k??a),Azadirachta indica A. Juss.(nimba) Fruit(phala),Trichosanthes dioica Roxb.(pa?ola)

Leaf(patra),Saussurea lappa Clarke(ku??ha) Root(m?la),Picrorhiza kurroa(ka?uk?, ku?ak?)

Rhizome(prakanda),Piper longum Linn.(pippal?) Fruit(phala),Melia azedarach Linn.(mah?nimba, kai?arya) Stem bark(k?n?atvak),Hemidesmus indicus (Linn.) R. Br.(s?riv? (utpalas?riv?))

Root(m?la),Pongamia pinnata (Linn.) Pierre(kara?ja, noda Linn. Syn.: Adhatoda vasica Nees(v?s?))

,Fumaria indica Pugsley Syn.: F.parviflora auct. pl. ,non Lam. (parpa?a bheda (y??.))

St.Bark,Leaf,Flower,Fruit&Root(Pancanga),Cryptolepis buchanani (k??as?riv?, jamb?patr? s?riv?) Stem

bark(k?n?atvak),Aconitum heterophyllum Wall. ex Royle(ativi??) Root(m?la),Fagonia cretica Linn. /

Alhagi pseudalhagi (Bieb.) Desv.(dhanvay?sa) St.Bark,Leaf,Flower,Fruit&Root(Pancanga),Trichosanthes

braceata (Lam.) Voigt Syn. T.palmata Roxb.(vi??l?, mah?k?la) ,Valeriana jatamansii Jones Syn.: V.

wallichii DC.(tagara, b?laka) Root(m?la), along with other ingredients.

D6:AK2/169A Vajrakam Tailam (see annexure)

Useful in the Treatment of following Diseases : Vata-kaphaja(v?takaphaja),Diseases of skin

(carmaroga),Sinus / Fistula (n???),

IPC Codes : A61K 125/00, A61K 129/00, A61K 131/00, A61K 135/00, A61K 31/00, A61K 35/22, A61K

Knowledge Known Since : 500 years

Bibliography : Gadanigraha?,

D7:MH3/137II Zimaad -e- Asl -us- Soos

Useful in the Treatment of following Diseases : Alopecia (Daa-al-Sa?lab),Skin Marks(Jild ke daag dhabbe),Septic wounds(Jurooh-e-Muta?finah),

IPC Codes : A61K 125/00, A61K 36/484, A61P 17/00, A61P 17/14, A61P 29/00, A61P 31/04, C01B 5/00

Knowledge Known Since : 200 years

Bibliography : Muheet Azam.

Keyword(s)/Ingredient(s) : Glycyrrhiza glabra Linn.(Rubb-al-Soos/Asl-al-Soos) Root(Beekh/Asl /Usool), Water(Aab),

D8:AK10/792 Khalitya Cikitsa

Useful in the Treatment of following Diseases : Alopecia (kh?litya),

IPC Codes : A61K 129/00, A61K 131/00, A61K 133/00, A61K 36/00, A61K 36/185, A61K 36/53, A61K 36/62, A61K 36/85, A61K 9/06, A61P 17/00, A61P 17/14

Knowledge Known Since : 200 years

Bibliography : Yogatrangini ,

Keyword(s)/Ingredient(s) : Nymphaea stellata Willd.(utpal(n?la)) Flower(pu?pa), Terminalia bellirica (Gaertn.) Roxb.(bibh?taka) Fruit(phala), Sesamum indicum Linn.(tila) Seed(b?ja/ phal?sthi), Ocimum basilicum Linn.(barbar?) Leaf(patra), Callicarpa macrophylla Vahl(priya?gu) Flower(pu?pa), Madhuca longifolia (Koen.) Macbr. Syn.: M. indica J.F. Gmel.(madh?ka) Stem bark(k?n?atvak),

D9:AT/1021 Vibh?takatalam

Useful in the Treatment of following Diseases : Premature grey hair / Canities(palita), Alopecia (kh?litya),

IPC Codes : A61K 125/00, A61K 129/00, A61K 131/00, A61K 133/00, A61K 135/00, A61K 36/00, A61P 17/14, C01G 21/21, C01G 49/00, C01G 49/14

Knowledge Known Since : 1000 years

Bibliography : Su?ruta Sa?hit?,

Keyword(s)/Ingredient(s) : triphal?, Terminalia chebula Retz.(har?tak?), Terminalia bellirica (Gaertn.) Roxb.(bibh?taka), Phyllanthus emblica Linn. Syn.: Emblica officinalis Gaertn.(?malak?), Barleria prionitis Linn.(saireyaka (p?ta pu?pa), sahacara) Flower(pu?pa), Syzygium cuminii (Linn.) Skeels(jamb?) Leaf(patra), Terminalia arjuna (Roxb.) Bedd.(arjuna) Stem bark(k?n?atvak), Cassia occidentalis Linn.(k?samarda) St.Bark,Leaf,Flower,Fruit&Root(Pancanga), Sesamum indicum Linn.(tila) Seed(b?ja/ phal?sthi), Eclipta prostrata (Linn.) Linn. Syn.: E. alba (Linn.) Hassk. (bh??gar?ja) Seed(b?ja/ phal?sthi), Mangifera indica Linn.(?mra) Seed(b?ja/ phal?sthi), Boerhaavia verticillata Poir.(punarnav? ?veta) Root(m?la), Nelumbo nucifera Gaertn.(kamala, prapau??ar?ka (sth?n?panna au?adhi)) Root(m?la), Solanum surattense Burm. F. Syn.: S. xanthocarpum Schrad. & Wendl.(ka??ak?r? (?veta praj?ti lak?ma?? sth?n?panna au?adhi)) St.Bark,Leaf,Flower,Fruit&Root(Pancanga), Iron sulphate(k?s?sa) , Iron(lauha) , Xeromphis spinosa (Thunb.) Keay Syn.: Randia dumetorum (Retz.) Lam.(madana, mainaphala) Seed(b?ja/ phal?sthi), Galena(a?jana) , Glycyrrhiza glabra Linn.(ya??imadhu, kl?taka (sth?n?panna au?adhi)) Root(m?la), Nymphaea stellata Willd.(utpal(n?la)) Root(m?la), Hemidesmus indicus (Linn.) R. Br.(s?riv? (utpalas?riv?)) Root(m?la), Jasminum sambac (Linn.) Ait.(mallik?, v?r?ik?, madayant? (sth?n?panna au?adhi)) Leaf(patra), Pterocarpus marsupium Roxb.(b?jaka (asana)) Heart wood(k???hamaji?),

Claim-1 of the present invention is related to A herbal composition for the treatment of alopecia and chronic skin disorders comprising of extract of Azadirachta indica, oil or alcoholic extracts of Berberis aristata, Curcuma longa, Glycyrrhiza glabra, black pepper. Hemedesmus Indicus, Jasminum officianale, Picrorhiza kurroa, Pongamia glabra, Prunus podnum, Rubia cordifolia, Saussrea lappa. Symplocus caratogoides, Terminalia chebula, Trichosanthus Diocia and Stellata wild and celastrus oil, sesame oil, mustard oil and olive oil.

Above cited documents from tkdl also discloses the use of these ingredients either alone or in combination for the treatment of alopecia and other skin disorders. There are lot of references in tkdl which shows the combination of these ingredients. Thus in view of known uses of these claimed ingredients a person skilled in the art can easily combine them and claim in composition form for the known traditional uses that is alopecia and skin disorders thus the claims 1-8 of the present invention lacks novelty and inventive step.

Claim- 1 falls u/s 3(e) of the Patents act, 1970 as the composition 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.

**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.**

**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.**

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.

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

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.

Abstract shall commence with the title of the invention.

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.

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 secton 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

- c) amendments 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 11/06/2014.
- 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.**