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Letter No.:-BIO-TECH/2013/

Date : 14/06/2013

To,
Anand & Anand,
Advocates,
B-41, Nizamuddin East, New Delhi-110013, India.

SUB : Examination Report

APPLICATION NUMBER : 662/DEL/2008
DATE OF FILING : 14/03/2008
DATE OF REQUEST FOR EXAMINATION : 17/02/2009
DATE OF PUBLICATION : 05/09/2008

With reference to the RQ No. 1337/RQ-DEL/2009 Dated 17/02/2009 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 :

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

D1:AK/2582 ?atapu?p?dya?gh?tam

Useful in the Treatment of following Diseases : Obesity (medov?ddhi),Elephantiasis / Filariasis (??pada),Enlargement of liver / Chronic hepatomegaly(yak?dd?lyodara),Diseases of spleen(pl?h?vik?ra),
IPC Codes : A61K 125/00, A61K 129/00, A61K 131/00, A61K 133/00, A61K 135/00, A61K 35/20,
A61K Knowledge Known Since : 200 years

Bibliography : Bhai?ajya Ratn?val? ,

Keyword(s)/Ingredient(s) : Foeniculum vulgare Mill.(madhurik?, mi?rey?) Fruit(phala), along with other ingredients

D2:AK/731 Mustak?dyamodaka?

Useful in the Treatment of following Disease:Obesity (medov?ddhi),
IPC Codes : A61K 36/899, A61K 125/00, A61K 131/00, A61K 133/00, A61K 135/00, A61K 35/20,
A61K 36/00.

Knowledge Known Since : 200 years

Ingredients :Foeniculum vulgare Mill.(madhurik?, mi?rey?) Fruit(phala),Piper betle Linn.(n?gavall?, cavya bheda) Leaf(patra), Piper betle Linn.(n?gavall?, cavya bheda) Leaf(patra), Cyperus rotundus Linn. /

Cyperus scariosus R. Br. / Cyperus arundinaceum Baker (mustaka, ga??ad?rv?) Stem tuber (k??akanda), along with other ingredients.

D3:AK/982 Kravy?darasa?

Useful in the Treatment of following Diseases : Obesity (medov?ddhi), Toxication due to contamination of food with bodily waste (garavi?a), Ama (?ma), Abdominal lump (gulma), Diseases of spleen (pl?h?vik?ra), Ascites (jalodara), Colic (??la), Vata-pittaja (v?tapittaja).

IPC Codes : A23C 15/00, A61K 131/00, A61K 33/00, A61K 36/00, A61K 36/38, A61K 36/67,

Knowledge Known Since : 200 years

Bibliography : Bh?rata Bhai?ajya Ratn?kara, Ayurvedic Formulary of India, B?hadrasar?jasundara?, Rasendracint?ma?ai?, Rasendras?rasa?graha?, ?yurveda S?rasa?graha?, Bhai?ajya Ratn?val?, Rasatantras?ra? Evam Siddhaprayogasa?graha?;

Keyword(s)/Ingredient(s) : Piper longum Linn. (pippal?), Piper longum Linn. (pippal?), Piper retrofractum Vahl Syn.: P. chaba Hunter (cavya), Plumbago zeylanica Linn. (citraka), Zingiber officinale Roscoe (?rdraka, ?u??h?), Mercury (p?rada) Purified (?uddha), Sulphur (Gandhaka) Purified (?uddha), Copper (t?mra) Calcined / Incinerated drug (Bhasma), Iron (lauha) Calcined / Incinerated drug (Bhasma), Citrus limon (Linn.) Burm.f. (jamb?ra phala, nimbu) Fruit (phala), Garcinia pedunculata Roxb. / Rheum australe D. Don Syn.: R. emodi Wall. ex Meissn. (amlavetasa) Fruit (phala), Ore-borax / Sodium baborate (?a?ka?a) Purified (?uddha), Ammonium chloride (vi?a lava?a), Piper nigrum Linn. (marica) Fruit (phala), Citrus limon (Linn.) Burm.f. (jamb?ra phala, nimbu) Fruit (phala),

D4:AK10/113 Trikatu

Useful in the Treatment of following Diseases : Obesity (medov?ddhi), Ozaena, sinusitis (HR) (p?nasa), Leprosy and other dermatoses (ku??ha),

IPC Codes : A61K 9/14, A61P 11/02, A61P 17/00, A61P 27/14, A61P 29/00, A61P 3/04, A61P 3/06,

Knowledge Known Since : 200 years

Bibliography : Yogatragini,

Keyword(s)/Ingredient(s) : trika?u, Zingiber officinale Roscoe (?rdraka, ?u??h?), Piper nigrum Linn. (marica), Piper longum Linn. (pippal?),

D5:RS6/951 Raga Sadhava

Useful in the Treatment of following Diseases : Obesity (medov?ddhi),

IPC Codes : A61K 131/00, A61K 135/00, A61K 36/00, A61K 36/185, A61K 36/22, A61K 36/38, A61K

Knowledge Known Since : 500 years

Bibliography : Kaiyadevanigha??au,

Keyword(s)/Ingredient(s) : Combination of Citrus medica Linn. (b?jap?ra) Fruit (phala), Punica granatum Linn. (d??ima) Fruit (phala) along with other ingredients

D6: M. A. Zaid, F. Afaq, D. N. Syed, M. Dreher, and H. Mukhtar, ?Inhibition of UVB-mediated oxidative stress and markers of photoaging in immortalized HaCaT keratinocytes by pomegranate polyphenol extract POMx, ? Photochemistry and Photobiology, vol. 83, no. 4, pp. 882-888, 2007.: In recent years there has been an increase in use of botanicals with antioxidant properties as skin photoprotective agents. Pomegranate (Punica granatum L.) fruit possesses strong antioxidant and anti-inflammatory properties.

D7: Rosmarinus officinalis L. (Family: Lamiaceae) have also been reported to have good anti-clastase activity (Baylac and Racine 2004).

D8: http://www.tkdil.res.in/tkdil/LangDefault/Ayurveda/Ayu_Cosmetics.asp

: It discloses the use of Sita (Cynodon dactylon) in Skin Care (Varnya):

D9: Wei, H.; Bowen, R.; Cai, Q.; Barnes, S.; Wang, Y. Antioxidant and antipromotional effects of the soybean isoflavone genistein. Proc. Soc. Exp. Biol. Med. 1995, 208, 124-130.

D10: Chung Hung Leea, Lin Yangb, Jin Ze Xua, Sai Ying Venus Yeunga, Yu Fluangc., Food Chemistry Volume 90, Issue 4, May 2005, Pages 735-741, Relative antioxidant activity of soybean isoflavones and their glycosides The present study compared the antioxidant potency of genistein and daidzein with their corresponding glycosides isolated from soybean seeds.

D11: (Hurley et al., 1998; Iritani et al., 1997). Along with the realization of many studies it has been observed that animals and humans fed with seeds of soybean tend to lose more weight than those who were fed animal protein such as casein.

D12: Source : http://cdn.intechopen.com/pdfs/15728/InTech-Soybean_and_obesity.pdf: The mechanisms of

action by which the soy protein isolates have beneficial effects on obesity are not completely clear yet. However, there are many studies confirming that different components included in the soybean have specific functions in the human body such as the absorption of the lipids, the insulin resistance, fat acid metabolism and other hormonal, cellular and molecular changes related with adipose tissue (Wang & Gonzalez, 2005).

D13:Chem Biol Interact. 2008 Feb 15;171(3):272-82. Epub 2007 Oct 22.

Quercus infectoria galls possess antioxidant activity and abrogates oxidative stress-induced functional alterations in murine macrophages.

D14:Kaur G, Athar M, Alam MS.: The present study reports the antioxidant activity of ethanolic extract of Quercus infectoria galls. The antioxidant potency of galls was investigated employing several established in vitro model systems. Their protective efficacy on oxidative modulation of murine macrophages was also explored. Gall extract was found to contain a large amount of polyphenols and possess a potent reducing power.

D15:Chandrika M. Liyana-Pathirana¹, Fercidoon Shahidi^{1,2,*}, Journal of the Science of Food and Agriculture, Volume 86, Issue 3, pages 477-485, February 2006, Antioxidant properties of commercial soft and hard winter wheats (*Triticum aestivum* L.) and their milling fractions: Thus wheat phenolics may serve as effective antioxidative components as measured by in vitro techniques. Copyright © 2005 Society of Chemical Industry.

Claim-1 of the present application is related to a herbal composition for waist and tummy firming comprising essentially the extracts and oils of the herbs Cyprus Pertinuis (Cyprus) oil, Ptychotis Ajowan (Ajowain) oil, Citrus aurantifolia (Lemon) oil, Foeniculum Vulgare (Black Pepper) oil, Punica Granatum Linn (Pomegranate) oil, Rosmarinus Officinalis (Rose Mary) oil, Geranium sylvaticum (Geranium) oil, Quercus infectoria (Majuphal) extract, Cynodon Dactylon (Doorva Grass) extract, Triticum Vulgare (Gehun Ankur), Spirulina Platensis (Spirulina) extract, Soja Hispida (Soya bean) extract.

Above cited documents also disclose the uses of these herbs in obesity treatment or cellulite reduction or has anti oxidant properties as discussed above thus find their uses in cosmetics in preparing creams/gels/oils for applying on different parts of the body for body firming/shaping. Present application also discloses the uses of these herbs in cellulite reduction and other advantages of these herbs as discussed above. Thus in view of known properties of the herbs in traditional knowledge a person skilled in the art can combine these herbs and claim the composition form for the known uses of these herbs. Thus in view of above discussion claims 1-7 of the present invention lacks novelty and inventive step.

Claims 1-7 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.

2 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.

3 **Claims 1-7 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.**

4 Claim-1 is not clearly worded in view of the fourth ingredient foeniculum vulgare. Common name of vulgare written in brackets is black pepper whereas actually black pepper is the common name of piper nigrum. It is also not properly supported by the description at page -6 where piper nigrum (black pepper)

ingredients is used in the composition. This inconsistency should be explained and the error needs to be rectified.

i) 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.

5 **ii) 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.**

iii) 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.

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

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

7 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 16/06/2014.

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.