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Letter No.:-BIO-TECH/2013/

Date : 09/04/2013

To,
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DELHI-110095, INDIA.

SUB : Examination Report

APPLICATION NUMBER : 1066/DEL/2009
DATE OF FILING : 25/05/2009
DATE OF REQUEST FOR EXAMINATION : 25/05/2009
DATE OF PUBLICATION : 01/01/2010

With reference to the RQ No. 4231/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 :

Subject matter of the claimed invention lacks 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 filed by TKDL :

(Source :TKDL)D1:AB/888 Kum?ry?sava? (01) (pl see annexure D1)

D1:It discloses the use of these ingredients along with other ingredients in the treatment of cough/bronchitis: Cinnamomum zeylanicum Blume(tvak),Elettaria cardamomum (Linn.), Piper longum Linn.(pippal?), Piper nigrum Linn.(marica), Alpinia galanga(Linn.), Vitis vinifera Linn.(dr?k??),Honey(madhu/k?audra),Jaggery & its preparations(gu?a), Curcuma longa(haridr?) .Above ngrdients are also claimed in the claim-1 of the present application.

1 D2:AJ/684 Draksa Avaleha (annexure D2)

Useful in the Treatment of following Diseases : Cough / Bronchitis(k?sa),

Ingredients used:Cinnamomum zeylanicum Blume(tvak),Elettaria cardamomum (Linn.)

Maton(s?k?mail?),Cinnamomum tamala Nees(tejapatra, Vitis vinifera Linn.(dr?k??), Curcuma longa, Piper longum , Alpinia galangal along with some other ingredients.

D3:AK2/591 Haritakyasava : (annexure D3)

Useful in the Treatment of following Diseases Cough / Bronchitis(k?sa)

Ingredients used :Vitis vinifera Linn.(dr?k??) Fruit(phala),Jaggery & its preparations(gu?a)

,Honey(madhu/k?audra) ,Piper longum Linn.(pippal?) Fruit(phala),Cinnamomum zeylanicum Blume(tvak)

Stem bark(*k?n?atvak*), *Elettaria cardamomum* (Linn.), *Cinnamomum tamala* Nees (*tejapatra*, *nalik?* (*sth?n?panna au?adhi*)) Leaf (*patra*), *Alpinia galanga* (Linn. along with some other ingredients).
D4:AM05/2074 *Vilvaadhi Ilagam-3* (please annexure D4)

Useful in the Treatment of following Diseases : Cough / Bronchitis (*Irupal, Kaasam*), Cough / Bronchitis (*Irupal, Kaasam*), Burning sensation (*Erivu*), (*Velluppunoi, Paandu, Ratha kuraivu*), Pyrexia (*Suram*), Distension of abdomen (*Vayiru*)
IPC Codes : A61K 131/00, A61K 133/00, A61K 135/00, A61K 35/20, A61K 36/185, A61K 36/23, A61K

Knowledge Known Since : 1000 years

Bibliography : *Athmarakshaamirtham*,

Keyword(s)/Ingredient(s) : *Zingiber officinale* Roscoe (*Inji, chukku*) Rhizome (*Ver Kombu, Matta nila thandu*), *Piper cubeba* Linn. f. (*Vaalmilaku, Thakkoolam, Ilathai, Thoorikai*) Fruit (*Pazham*), *Cinnamomum wightii* Meissn. (*Sirunagappu*) Flower Bud (*Poo Mokku*), *Piper longum* Linn. (*Thippili, Pippili*) Fruit (*Pazham*), *Alpinia officinarum* Hance (*chitrarathai, Channarashttam, Irattai*) Rhizome (*Ver Kombu, Matta nila thandu*), *Piper nigrum* Linn. (*Milagu*) Root (*Ver*), *Cuminum cyminum* Linn. (*Seerakam, Asai, Seeri, Posanakudori, Upakumba peesam, Pittha naasini, Prathivikaa, Methiyam*), *Strychnos potatorum* Linn. f. (*Thetraan kottai, Illam, Akkolam, Sillam, Teru, Kadali*) Root (*Ver*), *Plumbago zeylanica* Linn. (*Chithiramoolam, Venkodi veli, Sitragam*) Root (*Ver*), *Elettaria cardamomum* (Linn.) *Maton* (*Yaelakkai, Aanji, Dhudi, Korangam*), *Syzygium aromaticum* (Linn.) Merr. & L.M. *Perry* (*Kiraambu, Lavangam, Anjugam, Urkadam, Thirali, Varaangam, Karuvai, Karuvapoo*) Flower Bud (*Poo Mokku*), *Pogostemon plectranthoides* Desf. (*Pachilai*) Leaf (*Ilai, Thazhai*), *Kaempferia galanga* Linn. (*Kacholam, Kacholakizhangu*) Tuber/bulb/corm (*Kizhangu*), *Cow* (*Pasu, Komaadhaa*) Clarified butter (*Nei*),

It discloses the role of piper, *Cinnamomum*, *Syzygium aromaticum* (synonym of *Eugenia caryophyllata*), *Elettaria*, *Alpinia* and *kaempferia* in the treatment of respiratory disorders as also claimed in present application.

D5:BS05/181 (see annexure D5):

Useful in the Treatment of following Diseases : Cough / Bronchitis (*Irupal, Kaasam*), Burning sensation (*Erichal*), Venereal disease (*Maega noi, Vettai noi*), Hypertrophic or chronic rhinitis/frontal sinusitis (*Mandaikutthu*),

Ingredients disclosed are *Cinnamomum*, *Kaempferia galanga* Linn. (*Kacholam, Kacholakizhangu*), *Alpinia*, *Elettaria cardamomum* (Linn.) along with other ingredients.

D6:RS8/614 *Mahajambu Gu??*

Useful in the Treatment of following Diseases : Disease with Kapha predominance (*kaphavik?ra*), Cough / Bronchitis (*k?sa*),

IPC Codes : A61K 131/00, A61K 36/61, A61P 1/12, A61P 1/14, A61P 11/00, A61P 11/06, A61P 11/08, A61P 11/12, A61P 19/00, A61P 21/00, A61P 21/06, A61P 29/00, A61P 3/02, A61P 31/00, A61P 37/08, A61P 7/10

Knowledge Known Since : 200 years

Bibliography : *R?janigha??au?*,

Keyword(s)/Ingredient(s) : *Syzygium formosum* (Wall.) Masam. Syn.: *Eugenia formosa* Wall. (*jambubheda*) Fruit (*phala*),

Claim-1 of the present application is related to a composition useful for treatment in chronic respiratory disorders such as cold cough, allergic, asthma, whooping cough, throat infection comprising; *Piper Nigrum*, *Piper Longum*, *Elettaria Cardamomum*, *Potassium Carbonate*, (*Chavarkaram*), *Manayola*, *Gurh*, *Cinnamomum Zeylanicum*, *Vitis Vinifera*, *Alpinia Galanga / Alpinia Calcarata*, *Eugenia Caryophyllaea*, *Kaempferia Galanga / Curcuma Zedoaria* Rose, *Curcuma Longa*.

Above cited documents also discloses the use of these said ingredients in different combinations for the treatment of respiratory disorders. There are lot of documents in the TKDL which discloses the use of these ingredients in combination form for the treatment of respiratory disorders as mentioned in the claim. Thus based on the prior art the combination of these plants would be obvious for the treatment of respiratory disorders. The combination of a plant with a known therapeutic effect with further plants with the same known therapeutic effect, wherein all plants are previously known for treating the same disease is considered to be an obvious combination.

Subject matter of the claims 1-4 which are related to composition and process of making composition by mixing these ingredients lacks inventive step in view of above discussed prior art.

Claims 1-4 falls u/s 3(e) of the Patents act, 1970 as the composition and the process defined 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. 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 falls under section 3(p) of the Patents Act, 1970 as medicinal property of all the extracts and the plants 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.

Claim-2 should clearly define the expression "proportionate ratio" so as to clearly ascertain the scope of the invention.

The practice of including an omnibus claim (claim no.3 to 4) does not have any legal basis under the Patents Act. In fact, such a claim cannot be allowed as per Section 10(4)(c) of the Act. As such claims are unclear, vague and unsearchable; it is desirable to avoid omnibus claims in a patent application.

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).

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 18) for such permission is available in website of national Biodiversity Authority.

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 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 section 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 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 09/04/2014.

- 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

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