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BUILDING
Plot No. 32, Sector-14, Dwarka
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Tel No. (091)(011)
28034304-06,22
Fax No. 011
28034301,28034302
E-mail : delhi-patent@nic.in
Web Site : www.ipindia.nic.in

Letter No.:-BIO-TECH/2013/

Date : 05/07/2013

To,
C/O DR. PARIKSHIT BANSAL
IPR CELL, DEPTT. OF PHARMACEUTICAL
TECHNOLOGY,
NIPER, MOHALI-160059 PUNJAB, INDIA.

SUB : Examination Report

APPLICATION NUMBER : 1922/DEL/2005
DATE OF FILING : 22/07/2005
DATE OF REQUEST FOR EXAMINATION : 01/06/2009
DATE OF PUBLICATION : 31/07/2009

With reference to the RQ No. 4413/RQ-DEL/2009 Dated 01/06/2009 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 from TKDL:

RD/618 Bhall?tak?valeha? (see annexure 1):it discloses all the 5 ingredients as claimed in claim-1 for the treatment of bronchitis.

AK10/637 Bhall?tak?valeha? (see annexure 2) :it discloses all the 5 ingredients as claimed in claim-1 for the treatment of bronchitis.

K10/637 Bhall?tak?valeha?

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

1 IPC Codes : A23, A61K 125/00, A61K 129/00, A61K 131/00, A61K 135/00, A61K 35/78, A61K 36/00, A61K 36/185, A61K 36/19, A61K 36/22, A61K 36/23, A61K 36/24, A61K 36/27, A61K 36/28, A61K Knowledge Known Since : 200 years

Bibliography : Yogatrangini .

Keyword(s)/Ingredient(s) : Psoralea corylifolia Linn.(b?kuc?),Seed(b?ja/ phal?sthi),Fagonia cretica Linn. / Alhagi pseudalhagi (Bieb.) Desv.(dhanvay?sa),Acorus calamus Linn.(vac?),Acacia catechu (Linn. f.) Willd.(khadira),Stem bark(k?n?atvak),Pterocarpus santalinus Linn. f.(raktacandana),Heart wood(k???hamajji?), panicultata (Burm.) Nees / Swertia chirayita (Roxb. ex Flem.) Karst.(bh? Wight. & Arn. / Chonemorpha fragrans (Moon) Alston Syn. C. macrophylla (Roxb.) G. Don. (m?rv?), Piper longum

Linn.(pippal?), Cassia fistula Linn.(?ragvadh), Alstonia scholaris (Linn.)R. Br.(saptapar?a), Abrus precatorius Linn.(gu?j?), Gloriosa superba Linn.(l??gal?), Pluchea lanceolata Oliv. & Hiern / Alpinia galanga(Linn.)Willd.(r?sn?), Pongamia pinnata (Linn.) Pierre(kara?ja, naktam?la,

AB/817 Ka??ak?r?gh?tam (03)

Useful in the Treatment of following Diseases : Paediatric asthma(b?la?v?sa), Paediatric cough(Bala kasa), Pyrexia(jvara), Anorexia (arocaka), Colic (?la), Disease with Kapha predominance(kaphavik?ra), IPC Codes : A61K 125/00, A61K 131/00, A61K 135/00, A61K 35/20, A61K 36/00, A61K 36/15, A61K Knowledge Known Since : 200 years

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

Keyword(s)/Ingredient(s) : Scindapsus officinalis Schott(gajapippal?) Fruit(phala), Piper longum Linn.(pippal?) Fruit(phala), Piper nigrum Linn.(marica) Fruit(phala), Glycyrrhiza glabra Linn.(ya??imadhu, kl?taka (sth?n?panna au?adhi)) Root(m?la), Acorus calamus Linn.(vac?) Rhizome(prakanda), Piper longum Linn.(pippal?) Root(m?la), Nardostachys Jatamansi (D.Don) DC.(ja??m??s?, mur? (sth?n?panna au?adhi)) Root(m?la), Piper retrofractum Vahl Syn.: P. chaba Hunter(cavya) Stem(k????a), Plumbago zeylanica Linn.(citraka) Root(m?la), Pterocarpus santalinus Linn. f.(raktacandana) Heart wood(k???hamajj?), Cyperus rotundus Linn. / Cyperus scariosus R. Br. / Cyperus arundinaceum Baker(mustaka, ga??ad?rv?) Stem tuber(k???akanda), Tinospora cordifolia Miers(gu??c?) Stem(k????a), Santalum album Linn.(candana (?veta)) Heart wood(k???hamajj?), Trachyspermum ammi (Linn.) Spragne(yav?n?) Seed(b?ja/ phal?sthi), Cuminum cyminum Linn.(?vetaj?raka) Fruit(phala), Sida cordifolia Linn.(bal?) Root(m?la), Zingiber officinale Roscoe(?rdraka, ?u??h?) Rhizome(prakanda), Vitis vinifera Linn.(dr?k??) Fruit(phala), Punica granatum Linn.(d??ima) Fruit(phala), Cedrus deodara (D.Don) G.Don(devad?ru) Heart wood(k???hamajj?), Clarified butter(gh?ta/sarpi) Cow(gau), 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), Solanum indicum Linn.(b?hat? (kerala)) St.Bark, Leaf, Flower, Fruit&Root(Pancanga), Clerodendrum divaricatum Jack Syn.: C. serratum Spreng. / Clerodendrum indicum (Linn.) O.Kuntze(bh?ra?g?) Root(m?la), Justicia adhatoda Linn. Syn.: Adhatoda vasica Nees(v?s?) Leaf(patra), Milk(dugdha/k??ra/payas) Goat(Vasta / Basta),

NA2/2891 Dawa-e- Baabchi Bara-e- Dama

Useful in the Treatment of following Diseases : Bronchial asthma(Zecq-al-Nafas Shu?bi/Zecq-al-Nafas/Rabw),

IPC Codes : A61K 131/00, A61K 36/487, A61P 11/00, A61P 11/06, A61P 11/08, A61P 37/08

Knowledge Known Since : 100 years

Bibliography : Khazaain al Advia,

Keyword(s)/Ingredient(s) : Psoralea corylifolia Linn.(Babchi) Seed(Tukhm/Bazr/Buzoor),

AT/2067 Gu?ar?sn?dileha?

Useful in the Treatment of following Diseases : Dyspnoea(?v?sa), Cough / Bronchitis(k?sa), Bronchial asthma(tamaka ?v?sa),

IPC Codes : A61K 125/00, A61K 131/00, A61K 35/78, A61K 36/00, A61K 36/185, A61K 36/28, A61K 36/67, A61K 36/74, A61K 36/87, A61K 36/9066, A61K 9/10, A61K 9/16, A61P 11/00, A61P 11/06, A61P 11/08, A61P 11/12, A61P 37/08

Knowledge Known Since : 1000 years

Bibliography : K??yapa Sa?hit? or Vrddhajivakiya Tantra ,

Keyword(s)/Ingredient(s) : Jaggery & its preparations(gu?a) , Pluchea lanceolata Oliv. & Hiern / Alpinia galanga(Linn.)Willd.(r?sn?) Leaf(patra), Piper longum Linn.(pippal?) Fruit(phala), Vitis vinifera Linn.(dr?k??) Fruit(phala), Piper nigrum Linn.(marica) Fruit(phala), Curcuma longa(haridr?)

Rhizome(prakanda), Rubia cordifolia Linn.(ma?ji??h?) Root(m?la), Sesamum indicum Linn.(tila) Seed(b?ja/ phal?sthi),

AB/718 K????dic?r?am (02)

Useful in the Treatment of following Diseases : Paediatric diarrhoea with fever(b?la jvar?tis?ra), Paediatric asthma(b?la?v?sa), Paediatric cough(Bala kasa), paediatric vomiting (b?lachardi),

IPC Codes : A61K 125/00, A61K 131/00, A61K 135/00, A61K 36/00, A61K 36/185, A61K 36/67, A61K 36/714, A61K 36/8905, A61K 9/14, A61P 1/08, A61P 1/12, A61P 11/00, A61P 11/06, A61P 11/08, A61P

11/10, A61P 11/12, A61P 11/14, A61P 29/00, A61P 31/00, A61P 37/08

Knowledge Known Since : 500 years

Bibliography : Bh?rata Bhai?ajya Ratn?kara ,?yurveda S?rasa?graha? ,

Keyword(s)/Ingredient(s) : Piper longum Linn.(pippal?) Fruit(phala),Aconitum heterophyllum Wall. ex Royle(ativi?) Root tuber(m?lakanda),Cyperus rotundus Linn. / Cyperus scariosus R. Br. / Cyperus arundinaceum Baker(mustaka, ga??ad?rv?) Stem tuber(k??akanda),Pistacia integerrima J.L.Stewart ex Brandis(karka?a??g?) Gall(k??ag?ha),

AB/720 K????dic?r?am (04)

Useful in the Treatment of following Diseases : Paediatric asthma(b?la?v?sa),Paediatric cough(Bala kasa),Paediatric pyrexia(b?lajvara),

IPC Codes : A61K 131/00, A61K 35/20, A61K 36/00, A61K 36/185, A61K 36/48, A61K 36/67, A61K 36/87, A61K 36/888, A61K 9/14, A61P 11/00, A61P 11/06, A61P 11/08, A61P 11/10, A61P 11/12, A61P 11/14, A61P 29/00, A61P 31/00, A61P 31/04, A61P 33/00, A61P 33/06, A61P 33/08, A61P 37/08, A61P 43/00

Knowledge Known Since : 100 years

Bibliography : Bh?rata Bhai?ajya Ratn?kara ,B?hat Nigha??u Ratn?kara ,?ryabhi?aka ,Nigha??uratn?kara?

Keyword(s)/Ingredient(s) : Piper longum Linn.(pippal?) Fruit(phala),Fagonia cretica Linn. / Alhagi pseudalhagi (Bieb.) Desv.(dhanvay?sa) St.Bark,Leaf,Flower,Fruit&Root(Pancang),Vitis vinifera Linn.(dr?k??) Fruit(phala),Pistacia integerrima J.L.Stewart ex Brandis(karka?a??g?) Gall(k??ag?ha),Scindapsus officinalis Schott(gajapippal?) Fruit(phala),

AK/1345 ?v?saku?h?rorasa? (1)

Useful in the Treatment of following Diseases : Cough / Bronchitis(k?sa),Dyspnoea(?v?sa),Paralysis of the larynx/ a stage of Asthma / Tuberculosis or cancer of the Larynx(svaraghna),Vata-kaphaja(v?takaphaja),Disease(roga/ vy?dhi),

IPC Codes : A61K 125/00, A61K 131/00, A61K 33/36, Knowledge Known Since : 200 years

Bibliography : Rasendras?rasa?graha? ,?yurveda S?rasa?graha? ,Bhai?ajya Ratn?val? ,

Keyword(s)/Ingredient(s) : trika?u,Zingiber officinale Roscoe(?rdraka, ?u??h?),Piper nigrum Linn.(marica),Piper longum Linn.(pippal?),Mercury(p?rada) Purified (?uddha),Sulphur(Gandhaka) Purified (?uddha),Aconitum chasmanthum Stapf & Holmes / Aconitum ferox Wall. ex Ser. (??gika vi?a) Root tuber(m?lakanda),Ore-borax / Sodium baborate(?a?ka?a) Purified (?uddha),Realgar/Red Arsenic Sulphide(mana??il?) Purified (?uddha),Piper nigrum Linn.(marica) Fruit(phala),

NA2/20VI Dawa-e- Aak8

Useful in the Treatment of following Diseases : Bronchial asthma(Zeeq-al-Nafas Shu?bi/Zeeq-al-Nafas/Rabw),

IPC Codes : A61K 131/00, A61K 135/00, A61K 36/27, A61K 36/67, A61P 11/00, A61P 11/06, A61P 11/08, A61P 37/08

Knowledge Known Since : 100 years

Bibliography : Khazaain al Advia.

Keyword(s)/Ingredient(s) : Calotropis gigantea (Linn.) Ait. f.(Madar/Aak) Vegetative buds / Young bud(Shagoofah/Ghunchah),Piper nigrum Linn.(Filfil (Safa'id/Siyah)) Fruit(Samar/Fawakeh),

Claims of the present invention are related to herbal composition for providing relief in respiratory disorders especially asthma, wherein the said composition comprises of five herbs viz. Acorus Calamus, Alpinia galanga, Psoralea corylifolia, Piper longum, and Piper nigrum present in equal quantity by weight in dry, powdered form.

Above cited document from TKDI also discloses the role of five herbs as claimed in claim-1 either alone or in combination form in the treatment of respiratory disorders.Thus in view of known properties of herbs combination of herbs is obvious foe a person skilled in the art.thus Claims 1-4 of the present application lacks both novelty and inventive step.

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.

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 in the form of herbal composition (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 1-4 fall under section 3(p) of the Patents Act, 1970 as medicinal property of all the herbs are known in traditional knowledge.

3

The invention as claimed is traditional knowledge and aggregation or duplication of known properties of traditionally known components.

i) 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.

ii) 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.

iii) 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.

5 Claims portion should start from the fresh page .Fresh pages of claims should be provided.

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 07/07/2014.

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.