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Date: 23/01/2013

Letter No.:-BIO-TECH/2014/

To.
L.S. DAVAR & CO.
PATENT AND TRADEMARKS ATTORNEYS,
5/I (IST FLOOR) KALKAJI EXTENSION, NEW DELHI-110019, INDIA.

SUB: Examination Report

APPLICATION NUMBER : 1735/DEL/2007

DATE OF FILING : 14/08/2007

DATE OF REQUEST FOR EXAMINATION : 18/11/2008

DATE OF PUBLICATION : 24/04/2009

With reference to the RQ No. 11257/RQ-DEL/2008 Dated 18/11/2008 in the above mentioned application for Grant of Patent , a) Examination has been conducted under Section 12 and 13 of the Patents Act 1970 . The following objections are hereby communicated

b) Objections:

1 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: D1:BP/1007 J?t?phal?dyava?ik?

Useful in the Treatment of following Diseases: All types(sarvaprak?rake), Ama(?ma), Disease(roga/vy?dhi), Disease with Vata predominance(v?tavik?ra), All types(sarvaprak?rake), Cough / Bronchitis(k?sa),

IPC Codes: A61K 125/00, A61K 129/00, A61K 131/00, A61K 133/00, A61K 33/00, A61K 36/00, A61K Knowledge Known Since: 500 years

Bibliography: Bh?rata Bhai?ajya Ratn?kara, B?hadrasar?jasundara?, Rasendras?rasa?graha?, Rasaratn?kara? Rasendra kha??am, Keyword(s)/Ingredient(s):),Piper nigrum Linn.(marica) along with other ingredients.

D2:AT/149 A??agu?ama??a?

Useful in the Treatment of following Diseases: Pyrexia(jvara),

IPC Codes: A61K 125/00, A61K 131/00, A61K 36/00, A61K 36/185, A61K 36/23, A61K 36/48,

Knowledge Known Since: 500 years Bibliography: ??r?gadhara Sa?hit?,

Keyword(s)/Ingredient(s): Coriandrum sativum Linn.(dh?nyaka) Seed(b?ja/phal?sthi),Piper nigrum Linn.(marica) Fruit (phala), Piper longum Linn. (pippal?) Fruit (phala), Vigna radiata (Linn.) R. Wilcz. Syn.: Phaseolus radiatus Linn. (mudga) Seed (b?ja/ phal?sthi),Zingiber officinale Roscoe(?rdraka, ?u??h?) Rhizome(prakanda),Rock salt / Indian rock salt(Saindhava lavana),Oryza sativa Linn.(??li) Fruit(phala),

D3:NA4/553 Joshanda Barae Zeegunnafs

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

IPC Codes: A61K 125/00, A61K 131/00, A61K 36/00, A61K 36/12, A61K 36/23, A61K 36/235,

Knowledge Known Since: 100 years

Bibliography: Quaraabaadeen Najm al Ghani,

Keyword(s)/Ingredient(s): Iris ensata Thunb.(Irsa/Sosan/Sosan Surkh/Sosan Khataai/ Kasoras/ Kasoras) Root(Beekh/Asl/ Usool), Hyssopus officinalis Linn. (Zufa/Zufah) St. Bark, Leaf, Flower, Fruit&Root (Nabat Musallam), Adiantum capillaris-veneris, Linn (Sha?r-al-Jinn/Persiaaushaan/Lehaa-al-Ghool/ Ardmaana/Lehyat-al-Himaar/Kazbara-al-Bair/Kazbara-al-Maa)

It discloses the role of Iris in bronchial asthma which is also a respiratory disorder like sinusitis.

D4:NA4/4316 Laoog Zufa

Useful in the Treatment of following Diseases: Bronchial asthma(Zecq-al-Nafas Shu?bi/Zecq-al-Nafas/ Rabw), Chronic cough (Su"aal-e-Muzmin),

IPC Codes: A61K 125/00, A61K 36/53, A61K 36/88, A61P 11/00, A61P 11/06, A61P 11/08, A61P 11/10, A61P 37/08, C01B 5/00

Knowledge Known Since: 100 years

Bibliography: Quaraabaadeen Najm al Ghani,

Keyword(s)/Ingredient(s): Hyssopus officinalis Linn.(Zufa/Zufah), Iris ensata Thunb.(Irsa/Sosan/Sosan/Sosan Surkh/Sosan Khataai/ Kasoras/ Kaseeras) Root(Beekh/Asl/Usool), Water(Aab), Honey(Shahad/A"sal),

D5:HG/492 ??lavajri??va?ik?

Useful in the Treatment of following Diseases: Diseases of Cough / Bronchitis(k?sa), sinusitis(HR)(p?nasa), Disease with Vata predominance(v?tavik?ra), Disease with Kapha predominance(kaphavik?ra), Disease with Pitta predominance(pittavik?ra),

IPC Codes: A61K 125/00, A61K 129/00, A61K 131/00, A61K 133/00, A61K 33/00, A61K 35/20, Knowledge Known Since: 500 years

Bibliography: Rasayoga S?gara, Bh?rata Bhai?ajya Ratn?kara, Rasaratn?kara? Rasendra kha??am,

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), Iron(lauha) Calcined / Incinerated drug (Bhasma), Ferula foetida regel(hi?gu)

Role of piper nigrum in treating sinusitis has been disclosed.

D6:HG/500 ???g?r?bhram (02)

Useful in the Treatment of following Diseases: sinusitis(HR)(p?nasa), Diseases of spleen(pl?h?vik?ra), Disease(roga/ vy? dhi), Disease with Kapha predominance(kaphavik?ra), Disease with Vata predominance(v?tavik?ra), Disease with Pitta predominance(pittavik?ra),

IPC Codes: A61K 125/00, A61K 131/00, A61K 133/00, A61K 33/00, A61K 36/00, A61K

Knowledge Known Since: 500 years

Bibliography: Bh?rata Bhai?ajya Ratn?kara, B?hadrasar?jasundara?,

Keyword(s)/Ingredient(s): trika?u, Zingiber officinale Roscoe(?rdraka, ?u??h?), Piper nigrum Linn. (marica), Piper longum Linn. (pippal?), Mica / Biotite(abhraka) Calcined / Incinerated drug(Bhasma), Cinnamomum camp

D7:. http://www.jcrows.com/handbook.html, Handbook of Traditional Tibetan Drugs

Their Nomenclature, Composition, Use, and Dosage

T.J.Tsarong

AUG-CHOS 7 - INCARVILLEA 7

Composition: Incarvillea younghusbandii, Carthamus tinctorius,

Carex sp., Carum carvi, Drosera pettata, Rho-

dodendron aff. cephalanthum, Iris ensata

Use and Action

? sudden deafness? tinnitus

Claims 1-7 of the present application lacks inventive step in view of above discussed prior art. Piper and Iris are traditionally known in the treatment of sinusitis and respiratory disorders as discussed in above cited documents. Thus it is obvious to combine these teachings and claims the combination of these two ingredients in the treatment of sinusitis.

Claim's 1-7 - fall(s) within the scope of such clause (d) of section 3 of the Patents (amendment) Act, 2005 as the claim define a herbal preparation of already known substances with no efficacy shown over these substances.

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 1-7 falls under section 3(p) of the Patents Act, 1970 as medicinal property of Piper Nigrum and Iris Ensata used in the claimed preparation are known traditionally. The invention as claimed is traditional knowledge and aggregation or duplication of known properties of traditionally known components.

Claims 1 to 7 fall u/s 3(e) of the Patents (Amended) Act, 2005 as the said claims defines a mere admixture 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.

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.

1)Source /geographical origin of the biological materials used in the specification should be provided in the specification. The required permission from the NBA should be provided.

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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.

The practice of including an omnibus claim (claim no.7) does not have any legal basis under the Patents Act. In fact, such a claim 6 cannot be allowed as per Section 10(4)(c) of the Act. As such claims are unclear, vague and unscarchable; it is desirable to avoid omnibus claims in a patent application.

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 8 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 c) from the date of issue of FER failing which you application will be treated as "Decmed to have been abandoned" under section 21(1) of the Act. The last Date is 23/01/2014.

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.