



2946/MUM/2009



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To,
CSR.D,PEOPLE'S GROUP
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SUB : Examination Report

APPLICATION NUMBER : 2946/MUM/2009
DATE OF FILING : 21/12/2009
DATE OF REQUEST FOR EXAMINATION : 11/08/2010
DATE OF PUBLICATION : 10/02/2012

With reference to the RQ No. 2542/RQ-MUM/2010 Dated 11/08/2010 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 :**

The subject-matter claimed in the present application relates to a Traditional Knowledge (TK), which is not a patentable subject-matter as per Section 3 (p) of the Patents Act, 1970 (as amended). Herbs used in the present invention such as Kalmegh (*Andrographis paniculata*), Nirgundi (*Vitex negundo*), Gurmar (*Gymnema sylvestre*), Mulethi (*Glycyrrhiza glabra*), Brahmi (*Bacopa monnieri*), Gorakhmundi (*Sphaeranthus indicus*), Shankpushpi (*Evolvulus alsinoides*), Dashmoola/Dasamula (roots of ten herbs, viz., *Desmodium gangeticum*, *Uraria picta*, *Solarium surattense*, *Solarium indicum*, *Tribulus terrestris*, *Aegle marmelos*, *Premna mucronata*, *Oroxylum indicum*, *Gmelina arborea*, *Stereospermum suaveolens*) are traditionally known for treating tuberculosis [see prior art retrieved from TKDL database:

D1: Hindustan Cha Vaidyaraja, Published by Ramesh Raghavan, Gajanan Book Depot, Bhavani Shankar Road, Dadar, Mumbai, 15th August, 1974, page 269;

D2: Nityanatha Siddha, Rasaratnakara Rasayanakhanda Comm. Indradeo Tripathi- Chaukhamba Amar Bharati (Varanasi) Ed. 2nd 1992, pages 81-82;

D3: Pala Kapya, Gajayurveda, page 302,

D4: Vagabha (Commentary by Arunadutta) edited by Bhisagacarya Harisastri Paradakara Vaidya: Chaukhamba Orientalia, Varanasi, Ed. 8th 1998 (time of origin 5th Century), page 618;

D5: Vrddhajivakiya Tantra - Edited & translated by P. V. Tiwari: Chaukhamba Visvabharati, Varanasi, Ed. 1st 1996 (time of origin 600 BC), page 187;

D6: Cakradatta - Translated by Indradeva Tripathi; Chaukhamba Sanskrit Samsthan (Varanasi), Ed. 4th 2002, pages 425-426;

D7: Rasayoga Sagara - Compiled & translated by Vaidya Paita Hariprapanna, Vol. 1; Krishnadas Academy, Varanasi, Ed. Reprint, 1999 (this book contains back references from 1000 BC to 20th century), page 430; and

D8: Vagabha, Commentary by Arunadutta, Edited by Bhisagacarya Harisastri Paradakara Vaidya: Chaukhamba Orientalia, Varanasi, Ed. 8th 1998 (time of origin 5th century), page 610.

The subject-matter claimed in the present invention is considered as a mere admixture of extracts derived from traditionally known herbs in absence of any disclosure on technical evidences relating to unexpected or synergistic effects, which is not a patentable subject-matter as per Section 3 (c) of the Act.

Claims 1-8 lack inventive step, as required u/s 2 (1) (j) of the Act, in view of teaching of the following documents retrieved from TKDL database:

D1: Hindustan Cha Vaidyaraja, Published by Ramesh Raghuvan, Gajanan Book Depot, Bhavani Shankar Road, Dadar, Mumbai, 15th August, 1974, page 269, which discloses a composition/formulation comprising Kalmegh (*Andrographis paniculata*) for treating tuberculosis.

D2: Nityanatha Siddha, Rasaratnakara Rasayanakhanda Comm. Indradeo Tripathi- Chaukhamba Amar Bharati (Varanasi) Ed. 2nd 1992, pages 81-82, which discloses a composition/formulation comprising Nirgundi (*Vitex negundo*) for treating tuberculosis.

D3: Pala Kapya, Gajayurveda, page 302, which discloses a composition/formulation comprising Gurmar (*Gymnema sylvestre*) for treating tuberculosis.

3 D4: Vagabha (Commentary by Arunadutta), Edited by Bhisagacarya Harisastri Paradakara Vaidya: Chaukhamba Orientalia, Varanasi, Ed. 8th 1998 (time of origin 5th Century), page 618, which discloses a composition/formulation comprising Mulethi (*Glycyrrhiza glabra*) for treating tuberculosis.

D5: Vrddhajivakiya Tantra - Edited & translated by P. V. Tiwari: Chaukhamba Visvabharati, Varanasi, Ed. 1st 1996 (time of origin 600 BC), page 187, which discloses a composition/formulation comprising Brahmi (*Bacopa monnieri*) for treating tuberculosis.

D6: Cakradatta - Translated by Indradeva Tripathi; Chaukhamba Sanskrit Samsthan (Varanasi), Ed. 4th 2002, pages 425-426, which discloses a composition/formulation comprising Gorakhmundi (*Sphaeranthus indicus*) for treating tuberculosis.

D7: Rasayoga Sagara - Compiled & translated by Vaidya Paita Hariprapanna, Vol. 1: Krishnadas Academy, Varanasi, Ed. Reprint, 1999 (this book contains back references from 1000 BC to 20th century), page 430, which discloses a composition/formulation comprising Shankhpushpi (*Evolvulus alsinoides*) for treating tuberculosis.

D8: Vagabha, commentary by Arunadutta, Edited by Bhisagacarya Harisastri Paradakara Vaidya: Chaukhamba Orientalia, Varanasi, Ed. 8th 1998 (time of origin 5th Century), page 610, which discloses a composition/formulation comprising Dasamula (ten herbs, viz., *Desmodium gangeticum*, *Uraria picta*, *Solarium surattense*, *Solarium indicum*, *Tribulus terrestris*, *Aegle marmelos*, *Premna mucronata*, *Oroxylum indicum*, *Gmelina arborea*, *Stereospermum suaveolens*) for treating tuberculosis.

In view of the teaching of D1-D8, herbs/plants used in the present invention are traditionally known for treating tuberculosis & thus, to combine such herbs/plants, which are directed to the same use, is a straight forward action for a person skilled in the relevant art. Therefore, the inventive step cannot be acknowledged for the subject-matter of claims 1-8.

4 Claims 1-8, as worded, are so vague & unclear that it is very difficult to understand as to for what protection is being asked for therein. Although it is not clearly evident from claim 1, but it appears to be drafted like a formulation/composition claim. However, claims 2-7, which refer back to claim 1, vaguely define in terms of method features. The claims on record do not contain any transitional phrase or other indication of where the preamble ends & the body of the claims begins. Claim 8 is neither directed to a process nor product & defines the subject-matter in terms of the result to be achieved, which is not allowable. Further, as per general practice of claim drafting, every claim must be drafted in a single sentence. However, this is not the case with the present application. Moreover, there are many clerical/typographical errors in claims, which are required to be corrected. Thus, claims 1-8 on record failed to meet the requirements of Section 10 (4) (c) of the Act.

5 The invention as disclosed in the specification uses biological material (herbs/plants) & hence, a necessary permission from the competent authority i.e. National Biodiversity Authority (NBA) shall be obtained.

6 Preamble to the description applicable for the complete specification shall be given on page 1 of the Form-2.

7 The statement of claims should be separated from the body of the complete specification i.e. the claims section must begin on a separate physical sheet.

If any corrections/amendments is made in any page of the specification that page should be freshly typed and filed in duplicate 8 along with a marked copy clearly highlighting the corrections/amendments made. However, a care should be taken that no new matter is added in the specification as originally filed.

9 Kindly note that you should submit the documents only after complying with the above requirements.

10 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.

11 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 c) 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 24/07/2013.

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. Dinesh P. Patil)

Asst. Controller of Patents & Designs

NOTE : All Communications to be sent to the Controller of Patents at INTELLECTUAL PROPERTY BUILDING S. M. Road,
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