





## GOVERNMENT OF INDIA PATENT OFFICE INTELLECTUAL PROPERTY BUILDING G.S.T. Road, Guindy Chennai - 600032

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Date: 28/12/2012

## Letter No.:-BIO-TECH/2013/

To, SURANA & SURANA INTERNATIONAL ATTORNEYS TECHNOLOGY LAW DIVISION, 224, N S C BOSE ROAD, 3RD FLOOR, NATIONAL INSURANCE BUILDING, CHENNAI-600 001.

SUB : Examination Report

APPLICATION NUMBER

721/CHE/2004

DATE OF FILING

23/07/2004

DATE OF REQUEST FOR EXAMINATION

08/10/2007

DATE OF PUBLICATION

07/07/2006

With reference to the RQ No. 3429/RQ-CHE/2007 Dated 08/10/2007 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:

Claims 1-13 are not patentable u/S 3(e) of the Patents Act, 1970, as there is no support in the description for any synergistic interaction between the constituents of the claimed admixture.

Claims should be characterized by their technical features. A claimed composition should be defined in terms of the constituents, their ratios etc. In instant Claim 1 which appears to be a product-by-process claim, the claims has been defined in

- 2 terms of the features of the process by which extracts were obtained. Additionally, the term "Glycyrrhiza" & "Picrorhiza" should be corrected as indicated therein. Subsequent claims are not clear with reference to use of terms like "proportion" in Claim 2, "a newly identified protein" in Claim 7.
- Claims are not patentable u/S 3(c) of the Act as they relate to extracts which amounts to discovery of a substance existing in nature.
- The invention, as disclosed in the specification, uses biological material from India, prescribed permission from the competent authority(National Biodiversity Authority, Chennai) should be obtained and a declaration to that effect should be made in paragraph 9 (iii) of Form-1.

Claims 1-14 are not patentable u/S 3(p) of the Act as the subject matter of claims relate to traditional knowledge. Glycyrrihza glabra, Allium sativum, Azadirachta indica, Picrorhiza kurroa, Annona Squamosa, Withania Somnifera, Piper betle and

- 5 Tinospora Cordifolia has been used traditionally as Imrnuno-potentiator / Immuno-modulator, Anti ageing/Anti oxidant and strength promoting through oral administration in the Indian system of medicine. Refer TKDL RS 15/45. SS 02/18, RS 8/304, AM 05/2116, SS 02/42, RS/5088, RS 7/39, SK 03/157, RK/99(Documents enclosed for reference).
- 6 Claim 14 is not patentable u/S 3(i) of the Act as it relates to a method of treatment.

Without prejudice to above mentioned objections, Claims lack inventive step u/S 2(1)(ja) of the Act, in view of above mentioned prior art documents. In the instant application an anti-retroviral herbal formulation comprising medicinal herbs like Glycyrrihza glabra, Allium sativum. Azadirachta indica, Picrorhiza kurroa, Annona Squamosa, Withania Somnifera, Piper betle and Tinospora Cordifolia is claimed. Cited prior art documents disclose use of these plants as Immuno-potentiator

Immunomodulator, Anti ageing/Anti oxidant and strength promotors. Irrespective of the method employed for extraction of the active ingredient from the plant, it is evident that the therapeutic effect of the plant and/or extracts is known from the cited prior art documents. It would have been obvious to a person skilled in the art to have extracted active ingredients from the plants known for their therapeutic activity and made a formulation with the motivation that combinations of medicinal plants/extracts would be more effective than each of the medicinal plants when applied separately.

Complete specification should fully and particularly describe the invention and its operation and use and the method by which it is to be performed. The complete specification should also disclose the best method of performing the invention known to the applicant and for which he is entitled to claim protection, as required U/S.10(4) of the Patents Act, 1970. Instant claims are not supported by the description. It is not clear what exactly comprises the composition. On page 13 of description, the composition

8 is named LBT/gatp-1/04, an effect might be seen so as to boost the immune system, but no further effect can be ascertained. Mode of action of the claimed composition against retrovirus in general and HIV in particular is not disclosed. Claims 1-6 are not supported by the description in that the reference to any anti-retroviral function is not disclosed. Claims 7-9 lack any support in the description in that they refer to "a newly identified protein" and active principles which have no basis in the description.

9 Latest status of foreign filing particulars, if any, should be communicated to the office at the earliest.

(a)Proof of right should be filed. (b)Pages of the Complete specification shall be serially numbered at the bottom of each page 10 starting from the cover page and ending with last page of claims as indicated therein. (c)Blank space in the Complete

specification should be scored out over your signature.

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 12 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 secton 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

- c) months from the date of issue of FER failing which you application will be treated as "Deemed to have been abandoned" under section 21(1) of the Act. The last Date is 30/12/2013.
- 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 SP Subramaniyan)

Asst. Controller of Patents & Designs

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