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Date: 31/01/2014

Letter No.:-BIO-TECH/2014/

To,
M/s. Avestha Gengraine Technologies Pvt. Ltd
Discoverer
9th Floor, Unit 3
International Tech Park
Whitefield Road
Bangalore - 560 066.

SUB: Examination Report

APPLICATION NUMBER : 1565/CHE/2006

DATE OF FILING : 30/08/2006

DATE OF REQUEST FOR EXAMINATION : 30/08/2010

DATE OF PUBLICATION : 28/11/2008

With reference to the RQ No. 6377/RQ-CHE/2010 Dated 30/08/2010 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:
- 1 Claim 1 is not patentable u/S 3(i) of the Patents Act, 1970 as it relates to method of treatment.
- 2 Claims 10-12 do not constitute an invention u/S 2(1)(j) of the Act.
- Claims 13-16 are not patentable u/S 3(e) of the Act as they relate to a mere admixture lacking support in the description for synergistic activity between the constituents.
- 4 Claim 9 is not definitive as it has been defined in terms of its functional features or intended use instead of its technical features.

 Claims 1-16 are not patentable u/S 3(p) of the Act as they relate to Traditional Knowledge. Use of Eugenia jambolana for treatment of diabetes and related disorders is traditionally known. Refer enclosed TKDL documents D1:AN2/226G, D2:

AN2/22612, D3:SR06/54, D4: RS17/828, D5:MH4/110A1.

Not withstanding above mentioned objections, claims 2-8 lack novelty/inventive step in view of prior art documents D1-D5. The use of organic solvent and aqueous extracts of Eugenia jambolana for treating diabetes and related disorders would have been obvious to a person skilled in the art from the teachings of the cited prior art documents. If the subject-matter as claimed relates to extracts/alkaloids and/or isolation of active ingredients of plants, which are naturally/inherently present in plants, such claims cannot be considered as novel and/or inventive when use of such plants is pre-known as part of teachings of Traditional Knowledge

- 6 (TK). When the subject-matter of claims relate to extracts of plant materials containing undefined active ingredients, such claims cannot be said to be novel if the use of such plants or plant materials is pre-known as a part of teaching of TK. However, if the claims relate to alkaloids and/or active principles obtained from the plant materials and structures of the said alkaloids and/or active principles are characterized, which do not form the part of the prior art, such claims cannot be said to involve an inventive step, since the use of said plant materials and their therapeutic effects are known from the teaching of TK. Thus, the prior art motivates the person skilled in the art to isolate the individual ingredients such as alkaloids, flavonoids, phyto-steroids, etc.
- 7 Source & Geographical origin of Biological materials in the specification should be disclosed.

If the invention, as disclosed in the specification, uses biological material from India, prescribed permission from the competent authority(National Biodiversity Authority) should be obtained and a declaration to that effect should be made in paragraph 9 (iii) of Form-1. If the declaration in Form-1 regarding the use of biological material from India is cancelled out by the applicant and the specification also states that the source and geographical origin of the biological material is not from India, the specification should be amended by way of incorporation of a separate heading/paragraph at the beginning of the description that the biological

- material used in the invention is not from India and should clearly specify the country of source and geographical origin of the same.
- 9 Claims 13-16 are not fully supported by the description, with working example for claimed composition and its preparation, as required u/s 10(5) of the Patents Act, 1970.
- 10 Form 3 should be filed within the prescribed period.

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 12 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 "Deemed to have been abandoned" under section 21(1) of the Act. The last Date is 02/02/2015.
- 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. Sharana Gouda)

Asst. Controller of Patents & Designs

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