1199/CHE/2006

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Date : 29/10/2013

Letter No.:-BIO-TECH/2014/

To,
M/S AVESTHA GENGRAINE TECHNOLOGIES PVT.LTD.
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International Tech Park,
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SUB : **Examination Report**

APPLICATION NUMBER	:	1199/CHE/2006
DATE OF FILING	:	07/07/2006
DATE OF REQUEST FOR EXAMINATION	:	01/07/2010
DATE OF PUBLICATION	:	27/01/2012

With reference to the RQ No. 4781/RQ-CHE/2010 Dated 01/07/2010 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 Claims as worded define a plurality of distinct inventions.

2 Without prejudice to above mentioned objection, Claims 1-3 are not patentable u/S 3(i) of the Act as they relate to a method of treatment.

3 Claims 4-10 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, and a process for making such an admixture.

4 Claims 11,12 do not constitute an invention u/s 2(1) (j) of the Act.

5 **Claims 1-16 are not patentable u/S 3(p) of the Act as they pertain to traditional knowledge. Use of Andrographis paniculata for treatment of bone related disorders like rheumatism is traditionallyknown. Refer enclosed TKDL document D3: AK/2955.**

Claims lack novelty/inventive step in view of cited prior art documents D 1: JP2000 034233, D2: CN 1689628, D3: AK/2955. D1 (refer abstract) discloses nitric oxide production inhibitor which comprises supercritical or solvent extract of specific plants especially of Andrographis paniculata which is used for prevention and/or treatment of rheumatoid arthritis etc. D2(refer abstract) describes the medical use of Andrographis paniculata extract (ethanol) for the treatment of osteoarthritis etc. D3 discloses the use of Andrographis paniculata for treatment of bone related disorders like Rheumatism.In view of the disclosure of above mentioned prior art documents, claims 1, 3, 4, 6, 8, 10, 11, 13-15 lack novelty.

6 **Claims 1-16 lack inventive step u/S 2(1)(ja) of the Act in view of cited prior art documents. The use of organic solvent and aqueous extracts of Andrographis paniculata for treating bone related disorders like rheumatism 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 (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 Claims 2, 5, 9 and 12 are not clear with reference to definitions of the specific extracts claimed, as the "code" intended to define the extracts is not clear on its own. These codes which appear to be some internal designation should be replaced by clearly defined extracts.

8 Claim 7 is not clear with reference to use of the phrase "an extract of the invention".

9 Source & Geographical origin of Biological materials in the specification should be disclosed.

10 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.

11 Claims 4-7 are not fully supported by the description,with working example for pharmaceutical formulation and its preparation, as required u/s 10(5) of the Patents Act, 1970.

12 Claim 16 does not sufficiently define the product as there is no technical features of the product are stated in it.

13 Form 3 should be filed within the prescribed period.

14 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.

15 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 secton 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 you application will be treated as "Deemed to have been abandoned" under section 21(1) of the Act. The last Date is 29/10/2014.

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. Sharana Gouda)

Asst. Controller of Patents & Designs

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