889/MUMNP/2010

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Letter No.:-BIO-TECH/2015/

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SUB : **Examination Report**

APPLICATION NUMBER	:	889/MUMNP/2010
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With reference to the RQ No. 3373/RQ-MUM/2011 Dated 22/09/2011 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 source and geographical origin of the biological material used in the present invention is not disclosed in the specification, which is required to be disclosed as per Section 10 (4) (ii) (D) of the Act. Further, the Applicants? agent has cancelled out the
1 declaration in Form 1 regarding the use of biological material from India. Therefore, a separate heading/paragraph at the beginning of the description in the complete specification shall be added that the biological material used in the alleged invention is not from India and should clearly specify the country of the source and geographical origin of the same.

2 The subject-matter of claims 1-22 lacks novelty and/or inventive step, as required u/s 2 (1) (j) of the Patents Act, 1970 (as amended), as being anticipated by and/or obvious in view of following documents:

D1: EP 1032408 A1;
D2: US 5401777 A;
D3: DESHPANDE U.R. *et al.*, Indian J Exp Biol. June 1998 Vol. 36, No. 6, pages 573-577;
D4: WO 03051380 A2;
D5: AFZAL M. *et al.*, Electronic Journal of Environmental, Agricultural and Food Chemistry, June 2007, Vol. 6, No. 6. pages 2109-2118;
D6: BUSSMANN R.W. *et al.*, J Ethnobiol Ethnomed. Nov 7 2006, Vol. 2:47, ISSN 1746-4269 [Retrieved December 10, 2008]. Retrieved from the internet: URL: http://www.ethnobiomed.com/content/2/1/47, See Additional file 1, page 19 URL: http://www.ethnobiomed.com/content/supplementary/1746-4269-2-47-s1.pdf;
D7: WO 04048358 A1;
D8: BASKAR, R. *et al.*, Indian J Exp Biol. May 2007, Vol. 45, No. 5, pages 480-485;
D9: Raintree Nutrition Monograph, March 2004, pages 1-10 [Retrieved December 10, 2008] Retrieved from the internet: URL: http://www.rain-tree.com/Graviola-Monograph.pdf; and
D10: MORA S. *et al.*, Pharmacol Biochem Behav. October 2005, Vol.82, No.2, pages 373-378.

D1-D4: Compositions comprising *Curcuma longa*:

D1 discloses a composition comprising an extract of *Curcuma longa* rhizomes (and three other components) for use in treating hepatic disorders, such as hepatitis, fatty liver, hepatic cirrhosis and hepatocarcinoma.

D2 discloses preparations of *Curcuma longa* rhizomes, containing as a principle ingredient, curcumin, for the treatment of chronic hepatitis and for its antioxidative effect in eliminating activated oxygen molecules and radicals.

D3 discloses the *in vivo* hepatoprotective effect of an extract of dry *Curcuma longa* rhizomes in carbon tetrachloride-induced liver damage.
D4 discloses the use of extracts of *Curcuma* rhizomes to combat free-radical neuronal injury; i.e. as a free radical scavenger.
D5 and D6: Compositions comprising *Cordia*:
D5 discloses both the antiradical and *in vivo* hepatoprotective activity of extracts of *Cordia myxa* on carbon tetrachloride- or thioacetamine-induced liver damage.
D6 examines the traditional use of medicinal plants in Northern Peru. The additional material describes the species encountered in Northern Peru, and their uses. The use of an extract of *Cordia lutea* flowers for the treatment of hepatitis is specifically described on page 19.
D7-D9: Compositions comprising *Annona*:
D7 describes a crude extract from the plant family Annonaceae, a method for producing the extract, and its use for treating liver cancer. One embodiment is the preparation of an extract from a species of the genera, *Annona*.
D8 discloses that an ethanolic extract from the leaves of *Annona muricata* possesses potent antioxidant activity, and that, as an effective free radical scavenger, its therapeutic potential may be augmented.
D9 discloses the ethnobotanical uses of the graviola tree (*Annona muricata*) leaf extracts, including the treatment of hepatic disorders.
D10: Method for obtaining a hydroalcoholic extract:
D 10 discloses the preparation of a plant hydroalcoholic extract by a method comprising drying and grinding fresh samples, extraction with a mixture of ethanol:water for 1 hour at 50?C in a bathing apparatus, repeating the extraction procedure twice, filtering the hydroalcoholic extracts, mixing them, evaporation under reduced pressure, and freeze-drying to obtain a lyophilized extract.
This application discloses herbal compositions and their use in the treatment of hepatitis C or hepatitis C and B. The herbal compositions comprise an extract of flowers, leaves, and roots from the plant species *Cordia lutea, Annona muricata* and *Curcuma longa* in a specific proportion; namely 8:1:1 by weight, as described in Example 4.
Novelty:
In view of any one of D1-D4, claims 1, 4, 6, and 9, in so far as they relate to a herbal composition comprising *Curcuma* or an extract of *Curcuma* [roots (or rhizomes)] are not novel. Further, the method for the treatment or prevention of hepatic disorders of claim 17, when referring to the use of a herbal composition comprising a *Curcuma* or an extract of *Curcuma* [roots (or rhizomes)] does not comply with requirement of novelty in view of any one of D1-D3.
In view of D6, claims 1, 2, 4, 6, 7, 9, and 17 relating to a herbal composition comprising *Cordia* or an extract of *Cordia* [flowers], and a method of treatment or prevention of hepatic disorders using said composition, are not novel.
In view of D5, claims 1, 2, 6, 7, and 17, relating to *Cordia* or a *Cordia* extract, and its use in prevention or treatment of hepatic disorders, do not comply with requirement of novelty.
In view of either of D8 and D9, claims 1, 4, 6, and 9, in so far as they relate to a herbal composition comprising *Annona* or an extract of *Annona* [leaves], are not novel. The composition of claims 1 and 6, relating to *Annona* or an *Annona* extract, do not comply with the requirement of novelty in view of D7. Further, the method for the treatment or prevention of hepatic disorders of claim 17, when referring to the use of a herbal composition comprising an extract of *Annona*, does not comply with the requirement of novelty, in view of either D7 or D9.
In view of D1, claims 18, 19, and 21, in so far as they relate to the use of a herbal composition comprising an extract of *Curcuma* to treat or prevent viral hepatitis, hepatitis B or C, or cirrhosis, do not comply with the requirement of novelty.
Claim 18, in so far as the claim relates to the use of a herbal composition comprising one species of *Curcuma*, *Cordia* or *Annona*, or an extract thereof, to treat a hepatic disorder caused by a viral infection, does not comply with the requirement of novelty in view of D2, D6, or D9, respectively.
Claim 21, in so far as it relates to the use of a herbal composition comprising one species of *Curcuma* or *Cordia*, or an extract thereof, to treat fibrosis or cirrhosis of the liver does not comply with the requirement of novelty, in view of D3 or D5, respectively.
Claim 22, in so far as it relates to the use of a herbal composition comprising an extract of one species of *Curcuma*, *Cordia*, or *Annona* to neutralize or prevent free radical formation, does not comply with the requirement of novelty, in view of D2 and D4 (Curcuma), D5 (Cordia) or D8 (Annona).
Therefore, in view of the above cited documents, claims 1, 2, 4, 6, 7, 9, 17, 18, 19, 21 and 22 do not comply with the requirement of novelty.
Inventive step:
As claims 1, 2, 4, 6, 7, 9, 17, 18, 19, 21 and 22 are not novel, it follows that they do not contain an inventive step.
D1-D4 independently disclose extracts of *Curcuma* roots (or rhizomes), D5 and D6 independently disclose extracts of *Cordia* (D6, *Cordia* flowers), and D7-D9 independently disclose extracts of Annona (D8 and D9, Annona leaves). The only combination disclosed and characterized in the present application as having a synergistic effect *in vitro* is one containing an hydroalcoholic extract of Cordia lutea flowers, Annona muricata leaves and Curcuma longa roots in a ratio of 8:1:1. An inventive step cannot be acknowledged for a combination of extracts that are not shown to have a synergistic effect in vitro. In view of the above documents, claims 3, 5, 8, and 10-12 do not comply with the requirement of inventive step.
In view of D10 and common general knowledge, claims 15 and 16 lack an inventive step. The differences between the method disclosed in D10 and as defined in the claims 15 and 16, are the provision of a particle size after grinding, and the length of time and temperature for obtaining a hydroalcoholic solution. These are well within the capabilities of a skilled technician, and are therefore, obvious.

Claim 19, in so far as it relates to the use of a herbal composition comprising an extract of one species of *Curcuma, Cordia,* or *Annona*, to treat hepatitis C, hepatitis B, or a combination of both, does not comply with the requirement of inventive step in view of D2, D6, or D9, respectively. It would be obvious to try to use an extract known to treat or prevent viral hepatitis in order to specifically treat or prevent hepatitis C, hepatitis B, or a combination of both.

Claim 20, in so far as it relates to the use of a herbal composition comprising an extract of one species of *Curcuma, Cordia*, or *Annona*, to treat non-viral hepatitis does not comply with the requirement of inventive step in view of D1 and D2 (*Curcuma*), D6 (*Cordia*), or D9 (*Annona*). It would be obvious to try to use an extract known to treat or prevent viral hepatitis in order to treat or prevent non-viral hepatitis.

In view of the above comments, claims 1-12 and 15-22 do not contain an inventive step.

Further, the subject-matter of claims 1-22 also lacks inventive step, as being obvious in view of documents retrieved from Traditional Knowledge Digital Library (TKDL) database:

(i) TKDL Formulation ID. No. PD01/47 (Karuvanga Parpam-1);
(ii) TKDL Formulation ID. No. KU1/125V285 (Huqna Shaeeri);
(iii) TKDL Formulation ID. No. NA4/1465 (Daw-e-yarqaan);
(iv) TKDL Formulation ID. No. VS01/40 (Sogai Roga Haram); and
(v) TKDL Exhibits 1 to 8 cited in a pre-grant opposition representation by Mr. V. K. Gupta, Senior Advisor & Director, TKDL, CSIR, New Delhi.

3 The subject-matter of claims 1-22 also lacks inventive step because: (a) combination of plants with known-therapeutic effect with further plants with the same known-therapeutic agents, wherein all plants are previously known for treating the same disease is considered to be an obvious combination; (b) in case individual ingredients are already known for the treatment of a disease as a part of traditional knowledge, then it is obvious that a combination product comprising these known ingredients with further plants with the same known therapeutic effect would be more effective than each of the medicinal plants when applied separately (additive effect); and (c) discovering the optimum or workable ranges of traditionally known ingredients by routine experimentation is not inventive.

4 The subject-matter claimed in claims 1-22 falls within the scope of statutorily non-patentable inventions u/s 3 (p) of the Act, as being directed to an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components. In this regards, Applicants? attention is drawn to the traditional knowledge related documents retrieved from TKDL.

5 The subject-matter of claims 17-22 falls within the scope of statutorily non-patentable inventions u/s 3 (i) of the Act, since it pertains to method of treatment of hepatic disorder.

6 The complete specification shall comply with the provision under section 10 (4) (a) and (b) of the Act with respect to requirements of full and particular disclosure of the invention, its operation or use and the method by which it is to be performed along with the best method of performing the invention by way of working examples known to the applicant in the complete specification.

Claims lack unity of inventions because there is no special technical feature that could be identified so as to form these inventions combined together and construed as single invention. The claims are directed to a plurality of inventive concepts as follows:

Group A - Claims 1, 4, 6, 9 (partly), 2, 7 (fully) and 17-22 (partly) are directed to a herbal composition for treating hepatic disorders comprising one species of Cordia and methods for the treatment or prevention of hepatic disorders or for neutralizing and preventing the formation of free radicals, using said composition;

Group B - Claims 1, 4, 6, 9, and 17-22(all partly) are directed to a herbal composition for treating hepatic disorders comprising one species of Annona, and methods for the treatment or prevention of hepatic disorders or for neutralizing and preventing the formation of free radicals, using said composition;

7 Group C - Claims 1, 4, 6, 9 and 17-22 (partly) are directed to a herbal composition for treating hepatic disorders comprising one species of Curcuma, and methods for the treatment or prevention of hepatic disorders or for neutralizing and preventing the formation of free radicals, using said composition;

Group D - Claims 1, 4, 6, 9 (partly), 3, 5, 8, 10-14 (fully) and 17-22 (partly) are directed to herbal compositions for treating hepatic disorders comprising a combination of one species of each of Cordia, Annona, and Curcuma and methods for the treatment or prevention of hepatic disorders or for neutralizing and preventing the formation of free radicals, using said composition;

Group E - Claims 15 and 16 are directed to a method for obtaining hydroalcoholic extracts from a plant organ for use in preparation of a herbal composition; and

Group F - Claim 22 (partly) is directed to a method for neutralizing free radicals and for preventing the formation of free radicals by using the herbal composition of claims 1-14.

8 The applicant is requested to clearly identify the amendments carried out, irrespective of whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based. If any amendments/corrections is made in any page of the specification that page should be freshly typed and filed in duplicate 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.

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 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 29/01/2016.

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

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