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Letter No.:-CHEM/2012/

Date : 28/08/2012

To,
GOPAKUMAR NAIR ASSOCIATES, NAIR
BAUG, AKURLI ROAD, KANDIVLI (EAST),
MUMBAI - 400 101.

SUB : Examination Report

APPLICATION NUMBER : 881/CHENP/2008
DATE OF FILING : 21/02/2008
DATE OF REQUEST FOR
EXAMINATION : 20/06/2008
DATE OF PUBLICATION : 28/11/2008

With reference to the RQ No. 3326/RQ-CHE/2008 Dated 20/06/2008 in the above mentioned
a) application for Grant of Patent , Examination has been conducted under Section 12 and 13 of the Patents Act 1970 , The following objections are hereby communicated

b) Objections :

Composition with enriched fraction of tetrahydrocurcumin and its tetrahydro analogs, useful for treating inflammatory diseases, extracted from the roots of *Curcuma longa*, has been disclosed along with its method of preparation. The application do not meet the requirement of section 2 (1) (j) of the Patents Act 1970 in that the subject matter of the claims do not involve an inventive step in view of the cited documents . I- Patent Documents D1- US5266344 (Abstract and claims) Relates tetrahydrocurcumin and a substance containing the same, which are produced from curcumin . This substance has characteristic properties such as strong antioxidative activity. The curcumin is being produced from a Zingiberaceae plant classified into *Curcuma longa* as a tropical product. The invention further relates to the production method. D2- US 5401777 (See I, 2, 5, 6 and 20 , column 1, lines 6-20, column 3, lines 67 and 68, column 4, lines 1-6, column 6, lines 63-68. 1-6 and 20)-

discloses preparations from curcuma longa or other plants containing curcumin can be used to treat diseases associated with excessive formation of leukotriene(s), and/or prostaglandin(s). D4- JP 07-206753 (abstract and description) discloses a demethylated compound of curcumin i.e

Dihydroxycurcumin having the o-dihydroxy structures, useful as a cosmetic or a food additive because it has anti-inflammatory action, antioxidant action, melanin formation-inhibitory action, obtained by demethylation of curcumin with boron tribromide in anhydrous dichloromethane to effect the reaction at -70°C.

II- Non-patent (Journal Documents) Curcumin exhibit several pharmacological properties. It is reported to be a natural antioxidant. Because of this activity, curcumin has been found to exhibit anti-mutagenic and anticarcinogenic properties. Moreover, curcumin is a good anti-inflammatory agent. (Ref.1-6) The higher antioxidant capacity values of tetrahydrocurcumin, among the main metabolites of curcumin, is well-known. The higher antioxidant capacity is ascribed to a possible involvement of the diketone moiety, in particular a H-atom donation from the -diketone moiety to a lipid alkyl or a lipid peroxy radical [7].

1. Nishigaki I, Kuttan R, Oku H, Ashoori F, Abe H, Yagi K. Suppressive effect of curcumin on lipid peroxidation induced in rats by carbon tetrachloride or Co60-irradiation, J. Clin.Biochem.Nutr. 13, 1922, 23-29.
2. Soudamini KK, Unnikrishnan MC, Soni KB, Kuttan R. Inhibition of lipid peroxidation and cholesterol control levels in mice by curcumin, Indian J. Physiol. Pharmacol. 36, 1922, 239-243.
3. Elisabeth K, Rao MNA. Oxygen radical scavenging activity of curcumin, Int. J. Pharm. 58, 1990, 240-247.
4. Nagabushan M, Amonker AJ, Bhide SV. In vitro antimutagenicity of curcumin against environmental mutagens, Food Chem. Toxicol. 25, 1981, 545-547.
5. Soudamini KK, Kuttan R. Inhibition of chemical carcinogenesis by curcumin, J. Ethnopharmacol. 27, 1989, 227-233.
6. Mukholadyay A, Basu N, Ghatak N, Gujral PK. Anti inflammatory and irritant activities of curcumin analogues in rats, Agents Actions, 12, 1982, 508-512.
7. Jayaprakasha GK, Rao LJ, Sakariah KK. Antioxidant activities of curcumin, demethoxycurcumin and bisdemethoxycurcumin. Food Chem., 98, 2006, 720-724.
8. Bioscience, biotechnology, and biochemistry vol. 59, no. 9, September 1995, pages 1609 - 1612.

From TKDL website Curcumin (diferuloxylmethane), isolated from turmeric (*Curcuma longa*) has been used for centuries in India and elsewhere as a dietary spice and as a herbal medicine. In Traditional Knowledge Digital Library (TKDL), there are several references where *Curcuma longa* has been used for treatment of inflammation, cancer and other Geriatric diseases is available.

1. lankapatiravana: "haridra arka gunah" key attributes of tkdl ak14/51b
2. madanapala: "haridra guna" key attributes of tkdl rs15/111
3. sadanandasarma: "suvarna bhasma amayika prayoga-32" key attributes of tkdl ak1/349fl pages 1 - 8
4. naginadasa chaganalala saha: "nagaradicurnam" key attributes of tkdl rg/608
5. anonymous: "hemasutakarasa" key attributes of tkdl vs/2043 pages 1 - 3
6. trimalla bhattacharya: "vasantkusmakar" key attributes of tkdl ak10/311 pages 1 - 4
7. nagindasa chaganalala saha: "agnimukhamlavanam" key attributes of tkdl ab/48 pages 1 - 3
8. nityanathasiddhah: "talyanavalehah" key attributes of tkdl ak/1378 pages 1 - 3
9. yadavaji trikamaji acarya: "vasant kusumakara rasah prayoga" key attributes of tkdl ak15/218a page 1
10. kali dasa: "haritakyadiyogahh (02)" key attributes of tkdl hg/1265 pages 1 - 3

The claimed composition and its source *curcuma longa* and its use in treatment of cancer and other free radical mediated diseases has already been disclosed in the cited documents. Hence the invention lacks inventive step.

2 Claims 1 and 2 and 11-14 attracts section 3(e) of Patent Act 1970.

3 Claims 14 and 15 claims for method of treatment, are not allowable U/S 3(i) of patent act 1970.

The subject matter of the present invention attracts section 3(p) of patent act 1970, as the use of the compounds isolated from the root of *Curcuma longa* is already known in treatment of various diseases like inflammatory diseases, cancer and geriatric diseases and as anti oxidant etc. as disclosed

in TKDL website. (Refer TKDL documents cited)

5 The process described in claims 3-10 is obvious as it contains (i) demethylation and (ii) hydrogenation steps which involve well-known reactants and reaction parameters, hence cannot be allowed U/S2(1j) of Patent Act 1970.

6 The invention lacks sufficiency of disclosure. It is not clear from the description how one could increase the % of one component alone (i.e TC or THTC), from a mixture of four different chemicals. The reaction mechanism is not clearly understood. The demethylation of the mixture will definitely affect the chemical structure of all the four components in the mixture. Therefore it is opined that the description does not meet the requirements of the Section 10 of the Patents (Amendment) Act 2005.

7 Abstract shall be prepared and submitted according to rule 13(7) of the Patents Rules, starting with a title comprising searchable concise summary within 150 words.

8 Reference to foreign Patent applications / Patents should be replaced by Indian specification or supplemented by equivalent description.

9 The application do not meet the requirement of section 10 (5) of the Patents Act 1970 in that the claims of the application are not fairly based on the matter disclosed in the specification.

10 The title is not consistent with the claims.

11 Pre-grant opposition has been filed for this application. As the Controller has decided to take the cognisance of the Pre-grant Opposition, the written statement of the opponent is hereby forwarded for your action. If you desire to contest you are required to file reply within non-extendable time limit of 3 months from the date of dispatch of this FER.

12 Claims should be prefaced with the word 'I/We claim?'

13 It is seen from the filed Form-1 that the applicant has failed to provide all the "DECLARATIONS" as scheduled in paragraph 9(iii) of the Form-1. According to one of the specified declarations as provided in Form-1, the applicant when USES THE BIOLOGICAL MATERIAL in performing the invention, needs to submit the necessary permission from the competent authority [herein it is National Biodiversity Authority- NBA] before the grant of patent. Hence you are requested to amend the Form-1 as stipulated and also you need to file the necessary permission from the authorities of NBA before the the date of deciding the grant of patent when there are no other objections for the grant of patent right to the applicant.

14 Application number should be mentioned in Form 3.

15 Latest status of foreign filing particulars should be communicated to this office at the earliest.

16 Application number should be mentioned in Form-5.

17 Fresh forms and other relevant documents, if any, in duplicate, in the name of the claimant should be submitted.

18 Form-6 filed by you has been taken on record. Consequently the individual applicant [natural person] is replaced by an applicant who is other than a natural person; herein it is LAILA NUTRACEUTICALS; hence you are requested to file the difference of the fees from the start of filing the application. Please note that the fee charged from a person other than the natural person is 4 times to the fee chargeable to a natural person. This action is required to be fulfilled under the provisions of the subrule 3 of Rule 7 of the Patents (Amendment) Rules, 2006. You are requested to provide in a tabular format from the date of filing the application till date including the Form-6 and

other petitions, if any, for comparative understanding the difference of the fee to be paid to this office. As understood from the International Application under PCT that the Indian Residents [who are found to be Nationals in the present case] have filed directly the International Application. Under the provisions of the Section 39 and to read with the Section 40 and further to read with the Section 118 of the Patents (Amendment) Act 2005, any Indian resident when intends to apply in any foreign
19 country needs to apply for a permission before doing so. If not under the provisions of the Section 40 the present application shall be deemed as abandoned irrespective of meeting all other requirements. Hence you are requested to submit a notarized copy or a certified copy from this office to place the same on record as far as this application is concerned to overcome the objection as herein raised under the provisions of the Sections 39 and 40.

It has been observed from the International application filed under PCT there are 4 applicants who are themselves are the inventors. During the National Phase one out of the 4 inventors has become
20 the sole applicant. It is surprisingly found that under the column 9 of Form-1 the applicant has assigned the invention to himself which is legally incorrect. Therefore the Form-1 shall amended accordingly.

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
21 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
22 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
c) 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 28/08/2013.

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.

(T V Madhusudhan)

Asst. Controller of Patents & Designs

NOTE : All Communications to be sent to the Controller of Patents at INTELLECTUAL PROPERTY BUILDING G.S.T. Road, Guindy Chennai-600032.

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