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Date: 11/09/2012

## Letter No.:-CHEM/2014/

To,
BASAVARAJ K. NANJWADE
DEPARTMENT OF PHARMACEUTICS
KLE UNIVERSITY"S
COLLEGE OF PHARMACY, BELGAUM 590 010,
KARNATAKA STATE,
INDIA.

SUB: Examination Report

APPLICATION NUMBER : 2509/MUM/2010

DATE OF FILING : 13/09/2010

DATE OF REQUEST FOR EXAMINATION : 13/09/2010

DATE OF PUBLICATION : 15/10/2010

With reference to the RQ No. 2883/RQ-MUM/2010 Dated 13/09/2010 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:

The subject matter of claims does not constitute an invention u/s 2(1) (j) of the Patents Act, 1970, as the claims 1 to 7 do not involve inventive step in view of the disclosures in following prior published document:

D1: TKDL (CSIR): AM05/1818 ?Soolaikattu Thylam?, Kandasamy Mudaliar, Aavialikkum Churukkam (Athmarakshaamirtha Vaithiya saarasang). Publisher:Palani Thandayuthapanib Devasthanam publications, Directorate of Indian systems of Medicine,

- 1 Chennai. (Edn: 1<sup>st</sup>. 1975), Page 468, 469.
  - D1 discloses the formulation/composition comprising Nigella Sativa as one of the ingredient for the treatment of arthritis and inflammation. Hence, the person skilled in the art can obviously combine this with Annona squamosa for getting the claimed multipurpose herbal composition. Therefore, the composition claimed in claims 1 to 6 and process claimed in claim 7 is lacking in inventive step.
- The composition claimed in claims 1 to 7 and 8 is not patentable u/s 3 (p) and also 3 (e) of the Patents Act, 1970 as it claims for the composition which in effect is from Traditional Knowledge [see D1].
  - As per the requirement u/s. 10(4) (ii) (D) you have to disclose the source and geographical origin of the biological material used in the invention.
  - Your attention is hereby invited to section 6 of the Biological Diversity Act 2002, which mandates that if a biological material procured from India is used in an application for patent, permission for making an application for the patent obtained from the
- National Biodiversity Authority should accompany the application or if not already submitted with the application, should be submitted before the grant of the patent. Also other actions/information as required by the NBA is to be fulfilled under intimation to this Office. The relevant application form for such permission is available in the website of National Biodiversity Authority [www.nbaindia.org].
  - In the present case it appears that no such approval has been filed with the Patent Office. Therefore, you are advised to act as per the provisions of the Biological Diversity Act, 2002.
  - Claim 8 does not sufficiently define neither process nor product and also this omnibus is not defining the scope of the invention for
- 4 which protection is sought and hence is not allowable u/s 10(4) (c) of the Act [Please see paragraph 05.03.16 (t) on page 44 of MPOPP version 01.11 published on March 22, 2011].
- 5 Form-1 filed is not marked/ticked the declarations given in paragraph 9 (iii) of Form-1, especially for the biological material.

- 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 7 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 11/09/2013.
- 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.

(Amitava Chakraborty)

Deputy Controller of Patents & Designs

NOTE: All Communications to be sent to the Controller of Patents at INTELLECTUAL PROPERTY BUILDING S. M. Road, Antop Hill Mumbai-400 037.

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