



GOVERNMENT OF INDIA
PATENT OFFICE
INTELLECTUAL PROPERTY
BUILDING
Plot No. 32, Sector-14, Dwarka
New Delhi - 110 078

Tel No. (091)(011)
28034304-06,22
Fax No. 011
28034301,28034302
E-mail : delhi-patent@nic.in
Web Site :
www.ipindia.nic.in

Letter No.:-CHEM/2015/

Date : 14/10/2014

To,
GROSER & GROSER,
PATENT AND TRADE MARK ATTORNEYS,
D-1/5 DLF QUTAB ENCLAVE, PHASE 1,
GURGAON.122 002, INDIA.

SUB : Examination Report

APPLICATION NUMBER : 2946/delnp/2009
DATE OF FILING : 04/05/2009
DATE OF REQUEST FOR
EXAMINATION : 17/09/2010
DATE OF PUBLICATION : 25/12/2009

With reference to the RQ No. 7079/RQ-DEL/2010 Dated 17/09/2010 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 :

- 1 Clearly disclose the source and geographical origin of the biological material, i.e. plant material/plants used in the claimed invention, in the complete specification that is whether said biological material is from India or not. If said biological material is from India permission from competent authority should be filed and if 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.
- 2 Claims 5 and 10 neither process nor product hence does not constitute an invention u/s 2(1)j of Indian Patents Act.
- 3 The expression "according to claim" as used in claims 1-10 should be replaced by the expression "as claimed in".
(i) Claims 1-10 fall within the scope of such clause (p) of section 3 of Indian Patents Act as claimed invention is based on traditional knowledge (as evident from the cited documents) and relates to duplication of traditionally known medicinal property of olive plant for the treatment of muscle pain, injury or soreness.
- 4 (ii) Claims 4 and 9 fall within the scope of such clause (i) of section 3 of Indian Patents Act as claimed invention relates to a method of treatment of humans/animals.

(iii) Claims 1-10 appear to fall within the scope of such clause (d) of section 3 of Indian Patents Act as claimed invention appears to be a mere discovery of new property or new use for a known substance i.e. olive extract.

(iv) Claims 1-3, 6-8 appear to fall within the scope of such clause (e) of section 3 of Indian Patents Act as claimed invention appears to be mere admixture of the claimed components.

5 Claims 1 and 6 do not sufficiently define the invention w.r.t. the nature and definition of the components present in the claimed composition. Though the preamble relates to nutraceutical composition said claims define only use of olive extract as a single component for the claimed pharmacological effect to be achieved. The claims should clearly define the nature and components of the extract so used rather than the functional effect to be achieved by using such extract.

Subject matter of the claims does not constitute an invention u/s 2(1) (j) as the claims lack novelty and inventive step in view of cited documents-

D1: Database TKDL- Following traditionally known formulations retrieved from TKDL comprising claimed plants used for treatment of muscle injury, pain, spasm and fatigue-

(i) Name of formulation- Dohn-ul- Babunaj; formulation ID- JA3/170 [see annex. D1 (i)] refers to a formulation containing olive (*Olea europaea* Linn.) along with one other ingredient used for the treatment of fatigue and as an analgesic and relaxant through oral administration.

(ii) Name of formulation- Joshaanda-e- Muhallil; formulation ID- AH3/558A [see annex. D1 (ii)] refers to a formulation containing olive (*Olea europaea* Linn.) along with few other ingredients used for the treatment of fatigue and as an analgesic through oral administration.

(iii) Name of formulation- Roughan -e- Habb -ul- Ghaar; formulation ID- MA2/632 [see annex. D1 (iii)] refers to a formulation containing olive (*Olea europaea* Linn.) along with few other ingredients used for the treatment of fatigue. Mode of administration is as directed by physician.

(iv) Name of formulation- Zaitoon-al- Zait; formulation ID- AN4/76A [see annex. D1 (iv)] refers to a formulation containing olive (*Olea europaea* Linn.) as a single ingredient used a nutritive. Mode of administration is as directed by physician.

(v) Name of formulation- Zaitoon; formulation ID- MA1/98 [see annex. D1 (v)] refers to a formulation containing olive (*Olea europaea* Linn.) as a single ingredient used a tonic and nutritive. Mode of administration is as directed by physician.

(vi) Name of formulation- Ramaad-ul- Teen; formulation ID- AH1/309C [see annex. D1 (vi)] refers to a formulation containing olive (*Olea europaea* Linn.) along with few other ingredients used for the treatment of bruise /injury through oral administration.

(vii) Name of formulation- Ghiza -e- Dawaaal Bara-e- Tashannuj; formulation ID- AA1/544 [see annex. D1 (vii)] refers to a formulation containing olive (*Olea europaea* Linn.) along with few other ingredients used for the treatment of cramp/convulsion/spasm through oral administration.

6 (viii) Name of formulation- Abzan Bara-e-Tashannuj; formulation ID- AA1/558C [see annex. D1 (viii)] refers to a formulation containing olive (*Olea europaea* Linn.) as a single ingredient used for the treatment of cramp/convulsion/spasm.

(ix) Name of formulation- Marookh Bara-e-Tashannuj Intilai; formulation ID- AA1/566A [see annex. D1 (ix)] refers to a formulation containing olive (*Olea europaea* Linn.) as a single ingredient used for the treatment of cramp/convulsion/spasm.

(x) Name of formulation- Masooh Namak Barae Thakaan; formulation ID- AH1/671E [see annex. D1 (x)] refers to a formulation containing olive (*Olea europaea* Linn.) as a single ingredient used for the treatment of fatigue.

D2: JP 2005058115 A discloses the use of olive extract for treating muscle fatigue as seasoning of food/beverage products.

D3: JP 58146241 A discloses the use of a composition comprising i.e. olive oil extract which is added to a chewing gum base for the recovery from muscle fatigue.

D4: WO 2006/053872 A1 discloses the use of hydroxytyrosol to retain or restore muscle health, for example preventing and/or treating muscle damage due to exercise.

D5: WO 03/020026 A discloses the use of a composition comprising extract of artemisia and further comprising olive leaf extract to increase muscle cell strength and muscle cell endurance and to prevent and reduce fatigue.

D6: WO 03/082259 A discloses pharmaceutical and food compositions comprising hydroxytyrosol (isolated from olive) for the treatment or prevention of neurodegenerative diseases.

D7: JP 2002153238 A discloses glutathione S-transferase inducing food or pharmaceutical composition which includes a fraction containing secoiridoid glycoside, e.g. oleuropein through extraction of an edible plant or a medicinal plant, e.g. olive, with an appropriate solvent.

D8: US6399116 B1

D9: EP1639902 A

D1-D4 discloses the use of olive extracts or compounds found in olive extracts for the same therapeutical use as claimed in the present application and D5-D6 discloses the pharmaceutical and nutraceutical compositions of hydroxytyrosol or olive extract. As per D8 and D9 antioxidant compounds used to reduce muscle fatigue are active also to suppress the rise in lactic acid value upon physical exercise hence in the light of cited documents D1-D9 it is obvious for a person skilled in the art to use the olive extract for promoting muscle health.

As per guiding principle 1 of "Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material", as issued by CGPDTM, 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. When the subject-matter of claims relates 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. In the present case olive plant is traditionally known for its medicinal properties for the treatment of muscle injury, pain, spasm and fatigue and also the constituents of the extract as claimed is not defined hence the claims lack novelty and inventive step in view of the cited documents. Further as per guiding principle-3 of said guidelines, in case an ingredient is already known for the treatment of a disease, then it creates a presumption of obviousness that a combination product comprising this known active ingredient would be effective for the treatment of same disease. In the claimed invention olive extract is traditionally known independently and in combination with each other for the treatment of muscle injury, pain, spasm and fatigue then it is necessarily expected that a combination comprising the said known plant extract along with known other components must be effective for treating such diseases as long as no surprising (superior) effect of the claimed composition vis-a-vis the already known products comprising extract of olive is shown, inventive merits cannot be acknowledged.

Also as per guiding principle 5 of above stated guidelines in case multiple ingredients are known to have the same therapeutic activity as per traditional knowledge, taking out one single component out of them cannot be considered as inventive. D1 discloses several multicomponent formulations wherein olive has been used along with few other ingredients for the treatment of muscle injury, pain, spasm and fatigue therefore it is obvious that one single component namely olive out of the said formulations again would have the same therapeutic activity.

7 F-13 filed for amendment in claims is not allowed as there is no support for the nutraceutically acceptable carrier in the specification hence examination report based on the claims as filed in PCT international application.

8 Form-26 or power of attorney should be filed as per rule 135 of the Patents Rules 2003 of Indian Patents Act.

9 Endorsement by or assignment from inventor in favour of the applicant should be filed.

10 Title should be deleted from page 2 of the complete specification and fresh retyped page should be filed.

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

11 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.

12 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 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 from the date of issue of FER failing which you

c) application will be treated as "Deemed to have been abandoned" under section 21(1) of the Act. The last Date is 14/10/2015.

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.

(Hardev Karar)

Deputy Controller of Patents & Designs

NOTE : All Communications to be sent to the Controller of Patents at INTELLECTUAL PROPERTY BUILDING Plot No. 32, Sector-14,Dwarka New Delhi - 110 078.