

2497/DELNP/2008



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Date : 25/02/2014

Letter No.:-CHEM/2014/

To,
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SUB : Examination Report

APPLICATION NUMBER : 2497/DELNP/2008
DATE OF FILING : 25/03/2008
DATE OF REQUEST FOR EXAMINATION : 25/08/2009
DATE OF PUBLICATION : 27/06/2008

With reference to the RQ No. 6915/RQ-DEL/2009 Dated 25/08/2009 in the above mentioned application for Grant a) 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 The expression "according to claim" as used in claims should be replaced by the expression "as claimed in".
Clearly disclose the source and geographical origin of the biological material, i.e. plant extracts and plants from which compounds isolated, 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
- 3 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.

DI: Formulations retrieved from Traditional Knowledge Digital Library:-

(i) **Formulation name: Nirgundyadi Udvardna** [formulation ID: AKI 1/4080] published in Vangasena - Commentator Shaligram Vaisya, Edited Shankar laiji Jain; Khemraj Shrikrishna Das Prakashan, Bombay, Edn. 1996 Pg 910 refers to a formulation containing rape mustard along with few other ingredients used as anti-wrinkle through local application.

(ii) **Formulation name: Nirgundyadiprayogah** [formulation ID: RG/732] published in Bharata Bhasajya Ratnakara - compiled by Naginadasa Chaganalala Saha, translated by Gopinath Gupta - Vol.-III, B. Jain Publishers,

New Delhi, Edn. 2nd. Reprint, August 1999. [This book contains back references from 1000 B.C to 20th century], page 210 refers to a formulation containing rape mustard (Brassica rapa Linn. Syn.: B. campestris Linn.) along with few other ingredients used as anti-wrinkle through local application.

(iii) **Formulation name: Marookh Khosha-e- Angoor** [formulation ID: MIH/93B] published in Ibn Al-Jaam"e-li-Mufradaat-al-Advia-wal-Aghzia, Vol. IV (13th century AD). Matba Amra, Cairo, Egypt, 1874 AD page 57 refers to a formulation containing wine grape (Vitis vinifera Linn.) along with few other ingredients used as cleanser of skin/hide through local application.

(iv) **Formulation name: Kundurugunaah** [formulation ID: RS/4057] published in Siddhabhesajamanimalah- commentary by Kaladhara Bhatta, Chaukhamba Krishnadas Academy, Varanasi, Edn. 3rd 2003, Pg 49 refers to a formulation containing Indian frankincense (Boswellia serrata Roxb. ex Coleb.) as a single ingredient used as beneficial for skin. Mode of administration is as directed by physician.

(v) **Formulation name: Taraavish-e-Shaakh-e-Angoor [formulation ID: NA2/220AD2]** published in Khazaain-al-Advia, Vol. I (20th century AD), Nadeem Yunus Printer/Sheikh Mohd Basheer & Sons, Lahore, 1911 AD page 625 refers to a formulation containing wine grape (*Vitis vinifera* Linn.) as a single ingredient used for the treatment of diseases of skin through local application.

(vi) **Formulation name: Tiksanaka Guna [formulation ID: RS8/1092]** published in Rajanighantauh - edited with Hindi commentary by Indradeo Tripathi; Krishnadas Academy, Varanasi, Edn. 2nd 1998, pages 552-553 refers to a formulation containing rape mustard (*Brassica rapa* Linn. Syn.: *B. campestris* Linn.) as a single ingredient used for the treatment of Diseases of skin. Mode of administration is as directed by physician.

(vii) **Formulation name: Roghan-e-Aak I [formulation ID: NA2/20E1]** published in Khazaain-al-Advia, Vol. I (20th century AD), Nadeem Yunus Printer/Sheikh Mohd Basheer & Sons, Lahore, 1911 AD page 385 refers to a formulation containing grape mustard (*Brassica rapa* Linn. Syn.: *B. campestris* Linn.) as a single ingredient used for the treatment of diseases of skin through local application.

(viii) **Formulation name: Candraprabha Udvartanam [formulation ID: RS22/1176]** published in Rasatantra- sarah Evam Siddhaprayogasangraha- part I; Krishan Gopal Ayurveda Bhawan; Edn 8th: 1990 [This book contains back references from 1000 B.C. to 20th century] Pg 876 refers to a formulation containing rape mustard (*Brassica rapa* Linn. Syn.: *B. campestris* Linn.) along with few other ingredients used for as Beneficial for skin through local application.

(ix) **Formulation name: Raughan-e-kaalonji [formulation ID: JA6/359X]** published in Khazaain-al-Advia, Vol III (20th century AD) Nadeem Yunus Printer/Sheikh Mohd Basheer & Sons, Lahore, 1926 AD Pg.390 refers to a formulation containing *Cocos nucifera* Linn. along with few other ingredients used for the treatment of diseases of skin through local application.

(x) **Formulation name: Raughan Bara-e-Amraaz-e-jild [formulation ID: JA6/852Z.10]** published in Khazaain-al-Advia, Vol III (20th century AD) Nadeem Yunus Printer/Sheikh Mohd Basheer & Sons, Lahore, 1926 AD Pg.697 refers to a formulation containing *Cocos nucifera* (Linn.) and black mustard (*Brassica nigra* (Linn.)) along with few other ingredients used for the treatment of maggots in diseases of skin through local application.

It is apparent from the said formulations that extracts of rape mustard, Frankincense and black mustard, wine grape are pre-known for their use for treatment of skin diseases and anti-wrinkle effect as part of teachings of Indian traditional knowledge.

D2: US 2004/014732 A1 discloses a composition for topical treatment of hormone related characteristics like hirsutism (see paragraph 23) comprising a 4-nitro-3-trifluoromethylphenyl perfluoroacylamino propanamide, wherein said perfluoroacyl group is from 2-3 carbon atoms and said propanamide group is substituted at the 2- carbon atom with at least one of hydroxyl and methyl and a cosmetically acceptable carrier (see claims 9 and 1-2), like vegetable oils, ethanol, isopropanol (see paragraph 26). The composition can further comprise plant extracts (see paragraph 25) comprising an antioxidant (resveratrol). Further D2 anticipates that the composition can comprise a cosmetically acceptable carrier (see claims 9 and 1), like vegetable oils, ethanol, isopropanol (see paragraph 26) and that the composition can further comprise plant extract and antioxidant (see paragraph 25).

D3: WO 01/58855 A1 discloses substituted phenylalanines are provided comprising an hydantoin, urea or 2-hydroxyl, 2-methylpropionyl group, dimers thereof and alkyl, polyfluoroamido and haloarylamino derivatives thereof, as well as radiolabeled derivatives thereof. The compounds bind specifically to the androgen receptor and find use in indications associated with the androgen receptor, such as cell hyperplasia dependent on androgens, hirsutism, acne and androgenetic alopecia.

D4: M. Sovak et al., "Fiuridil, a Rationally Designed Topical Agent for Androgenetic Alopecia: First Clinical Experience", *Dermatologic Surgery*, vol. 28, no. 8, August 2002, pages 678-685.

D5: M. Sovak et al., "Development of Fluridil, a Topical Suppressor of the Androgen Receptor in Androgenetic Alopecia", *Drug Development Research*, vol. 59, 2003, pages 292-306.

D6: US 6184249 B1 discloses a skin care composition of cosmetically acceptable components for topical treatment of hirsutism comprising: an effective amount of a physiologically acceptable 4-nitro-3-trifluoromethylphenyl substituted perfluoroacylamino propanamide, wherein per fluoroacyl group is from 2-3 carbon atoms and said propanamide group is substituted at the 2-carbon atom with at least one of hydroxyl and methyl; a vehicle comprising a major amount of at least one naturally occurring refined oil, a triglyceride oil fraction and sufficient alkanol of from 2-3 carbon atoms to provide an at least substantially homogeneous mixture (example 21 and 28; col 6, ln 52-59; col 5, ln 13-15; col 7, ln 40-41).

D7: US 2005/025737 A1 discloses cosmetic compositions composed of melon fruit extract in combination with magnesium ascorbyl phosphate (MAP). These compositions may be preventative as well as reparative in treating wrinkles and other signs of aging of the skin, for the face and other areas of the body, as well as providing other beneficial effects to the skin. In one exemplary embodiment, the melon extract is obtained from a cucumis melo variety obtained by genetic crossing, such as the 95L.S444 line, or one of the hybrids obtained from this line. In another exemplary embodiment, the melon extract may be produced using only the melon pulp without any solvent and may be coated into microgranules with a vegetable fat. Further D8 teaches about effective amount of at least one physiologically acceptable antioxidant, naturally occurring plant extract in the skin care composition (para [0002]; [0011]).

D8: US6472415 discloses topical treatment of acne with a composition comprising compound BP766 (Sheet 2, Fig. 2) and a compound with the core structure matching the instant claims (col 6, lines 1-67). Further it also teaches that therapeutic compositions can be formulated in accordance with conventional ways (col9, lines 35-40), and conventional carriers include isopropanol, etc. (col 9, lines 43-46).

D9: US5955109 disclose treating acne (col 2, lines 1-5) with a topical composition comprising vitamin A, vitamin E, and isopropanol (col 11, Table 2).

D10: CN1137389 discloses treating acne externally (topical) with a composition comprising frankincense (see Abstract, full translation has been ordered).

D11: JP2005060334 discloses prevent acne with a cosmetic (topical) composition comprising *Polygonum cuspidatum*.

D12: US 2004/0009241 disclose treating acne with an external (topical) (see Abstract) composition comprising *Cocos nucifera* (col 6, Table 1).

D13: US 2004/0131710 disclose treating acne topically with a composition comprising non-denatured soybean extract (inherently contains an unsaponifiable fraction) (the same as *Glycine soja*, see Wikipedia online) (claims 10 and 20). D13 further discloses compositions comprising soybean milk, PEG 6-capric/caprylic triglycerides, and vitamin E acetate (Tables A and B)

D14: US 2005/0048138 disclose preventing acne topically with a composition comprising capric triglycerides, and grape seed oil (col 7, Example 10).

(i) Claims fall within the scope of such clause (p) of section 3 of Indian Patents Act as claimed invention is based on the traditionally known properties of claimed extracts for treatment of wrinkles and other diseases of skin effect (as disclosed in the cited documents).

4 (ii) Claims 15-17 fall within the scope of such clause (i) of section 3 of Indian Patents Act as claimed method relate to treatment of skin.

(iii) Claims 1-14 fall within the scope of such clause (e) of section 3 of Indian Patents Act as claimed composition appears to mere admixture of the claimed components.

5 Claim-1 does not sufficiently define the invention w.r.t. the chemical structure of the compound and the definition of the vehicle and antioxidant present in the claimed composition. Further definition and amount of the all the components present in the claimed composition should be given in claim-1.

6 Claims 7-10, 11, 12 and 13 goes beyond the scope of claim-1.

7 Claims not allowable u/s 10(4)(a) of Indian Patents Act as the complete specification not fully and particularly describe the invention w.r.t. the claimed compositions and their therapeutic effect as specification lacks support for the numerous variations in composition based on the definition and pharmacological effect so claimed.

8 Form-3 filed on 11/12/2009 cannot be taken on record as the same not filed within prescribed time limit.

9 Extraneous matter like PCT application details on pages of complete specification, should be deleted and fresh retyped pages should be filed.

10 It is seen from the filed Form-1 that the applicant has failed to furnish declarations as scheduled in paragraph 9 of the Form-1, the said declarations, specifically under para 9(iii), have to be mandatorily either affirmed or cancelled out .

11 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.

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.

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 your application will be treated as "Deemed to have been abandoned" under section 21(1) of the Act. The last Date is 25/02/2015.

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
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