

2749/DEL/2008



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To,
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SUB : Examination Report

APPLICATION NUMBER : 2749/DEL/2008
DATE OF FILING : 04/12/2008
DATE OF REQUEST FOR
EXAMINATION : 18/08/2010
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- With reference to the RQ No. 6230/RQ-DEL/2010 Dated 18/08/2010 in the above mentioned 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
 - Objections :

- 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 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: Database TKDL- Following traditionally known formulations retrieved from TKDL comprising claimed plants used as aphrodisiac and treatment of various sexual disorders-

(i) Name of formulation- Kharjura Purana Paka; formulation ID- RS17/2367 [published in Smkaradajisastripade; Aryabhisaka - Gujarati Edited (Hindustani No Vaidyaraja) Translation by Hariknshna Bhagwan Lal Vyas; Sastu Sahitya Vardhaka Karyalaya, Bhadra, Ahmedabad, Edn. 12th, 1957, page 176-177] refers to a formulation containing *Mucuna pruriens* Linn, *Withania somnifera* Linn, *Hygrophila auriculata* Schum, *Astercantha longifolia* Linn, *Myristica fragrans* Houtt, *Tribulus terrestris* Linn., *Curculigo orchioides* Gaertn *withania somnifera* Linn and *Anacyclus pyrethrum* along with few other ingredients used for the treatment of seminal disorders, oligospermia and impotency through oral administration.

(ii) Name of formulation- Puspadhanvarasah(5); formulation ID- VS/205 [published in Rasayoga Sagara - Compiled and Translated by Vaidya Pandita Hariprapanna Ji, Vol.-II; Krishnadas Academy, Varanasi, Edn. Reprint, 1998. (This book contains back references from 1000 B.C.to 20th century), page 59] refers to a formulation containing *Mucuna pruriens* Linn, *Withania somnifera* Linn, *Hygrophila auriculata* Schum, *Astercantha longifolia* Linn, *Myristica fragrans* Houtt, *Tribulus terrestris* Linn., *Curculigo orchioides* Gaertn, and *Anacyclus pyrethrum* along with few other ingredients used as aphrodisiac through oral administration.

(iii) Name of formulation- Trailokyasamohana Rasah; formulation ID- AK1/762 [published in Sadanandasarma; Rasatarangini- , Kasinathsastri, Motilal Banarasidas, Varanasi, Ed. 11th 1979 (Reprinted-Delhi, 2000), page 726-727] refers to a formulation containing *Tribulus terrestris* Linn, and *Mucuna pruriens* Linn, along with few other ingredients used for the treatment of male infertility and used as semen retaining, aphrodisiac through oral administration.

(iv) Name of formulation- Narikelapakah; formulation ID- RG/657 [published in Bharata Bhaisajya 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 183] refers to a formulation containing *Mucuna pruriens* Linn, *Hygrophila auriculata* Schum, *Astercantha longifolia* Linn, *Myristica fragrans* Houtt, *Tribulus terrestris* Linn, and *Anacyclus pyrethrum* along with few other ingredients used as aphrodisiac and used for the treatment of male infertility through oral administration.

(v) Name of formulation- Vajikarovatakah; formulation ID- RS/2173 [published in Bharata Bhaisajya Ratnakara- Compiled by Naginadasa Chaganalala Saha, Translated by Gopinath Gupta - Vol.-IV; B. Jain Publishers, New Delhi, Edn. 2nd, Reprint, August 1999 (This book contains back references from 1000 B.C.to 20th century), page 817,818] refers to a formulation containing *Mucuna pruriens* Linn, *Hygrophila auriculata* Schum, *Astercantha longifolia* Linn, *Myristica fragrans* Houtt, *Tribulus terrestris* Linn, along with few other ingredients used for the treatment of oligospermia , impotency and male infertility and used as aphrodisiac through oral administration.

(vi) Name of formulation- Habb-e- Mumsik; formulation ID- MA3/165 [published in Mohammad Kabiruddin; Bayaaz-e-Kabir, Vol. II (Compiled), Daftar-al- Maseeh, Karol Bagh, New Delhi, 1938 AD Pg 54] refers to a formulation containing *Myristica fragrans* Houtt and *Anacyclus pyrethrum* DC along with few other ingredients used for the treatment of premature ejaculation through oral administration.

(vii) Name of formulation- Safoof Bara-e-jiryan; formulation ID- JA6/58811 [published in Mohammad Najmul Ghani Khan; Khazaain-ai-Advia, Vol III (20th century AD), Nadeem Yunus Printer/Sheikh Mohd Basheer & Sons, Lahore, 1926 AD Pg 608] refers to a formulation containing *Tribulus terrestris* Linn along with one other ingredient used for the treatment of premature ejaculation, spermatorrhoea and nocturnal emission through oral administration.

(viii) Name of formulation- Halwa Muqawwi Baah; formulation ID- BA3/642 [published in Mohammad Akmal Khan; Qaraabaadeen Azam wa Akmal (20th century AD), Matba Siddiqi, Delhi/Matba Mustafai, Delhi, 1909 AD Pg 98] refers to a formulation containing *Mucuna pruriens* Linn and *Myristica fragrans* Houtt along with one other ingredient used for the treatment of premature ejaculation and used as aphrodisiac through oral administration.

(ix) Name of formulation- Atmagupta (Bija): formulation ID- RG/3669 [published in The Ayurvedic Pharmacopoeia of India- Part I, vol. III Ed. First 2001, Govt. of India, Ministry of Health & Family Welfare (This book contains back references from 1000 B.C. to 20th century), pages 23-24] refers to a formulation containing *Mucuna pruriens* Linn as a single ingredient used for the treatment of male infertility and used as aphrodisiac. Mode of administration is as directed by physician.

(x) Name of formulation- Jatiphala; formulation ID- RG/3533 [published in Mahendra Bhaugika; Dhanvantarinighantau - Edited by P.V. Sharma; Translated by Guru Prasad Sharma; Chaukhambha Orientalia, Varanasi, Edn. 3rd, 2002 Pg 97] refers to a formulation containing *Myristica fragrans* Houtt as a single ingredient used as aphrodisiac. Mode of administration is as directed by physician.

(xi) Name of formulation- Vallabhagutika; formulation ID- RS/1685 [published in Bharata Bhaisajya Ratnakara- Compiled by Naginadasa Chaganalala Saha, Translated by Gopinath Gupta - Vol.-IV: B. Jain Publishers, New Delhi, Edn. 2nd, Reprint, August 1999 (This book contains back references from 1000 B.C. to 20th century), page 609] refers to a formulation containing *Mucuna pruriens* Linn, *Hygrophila auriculata* Schum, *Myristica fragrans* Houtt, *Tribulus terrestris* Linn, *Curculigo orchiodides* Gaertn, and *Anacyclus pyrethrum* along with few other ingredients used as aphrodisiac and used for the treatment of impotency.

(xii) Name of formulation- Kesarpaka; formulation ID- AB/811 [published in Bharata Bhaisajya Ratnakara- Compiled by Naginadasa Chaganalala Saha, Translated by Gopinath Gupta - Vol.-I: B. Jain Publishers, New Delhi, Edn. 2nd, Reprint, August 1999 (This book contains back references from 1000 B.C. to 20th century), page 249] refers to a formulation containing *Mucuna pruriens* Linn, *Myristica fragrans* Houtt, *Tribulus terrestris* Linn, *Withania somnifera* and *Anacyclus pyrethrum* along with few other ingredients used as aphrodisiac.

(xiii) Name of formulation- Majoon-e-Kharos; formulation ID- MHI/3380A [published in Haj-al-Amraaz (18th century AD), Afzal-al-Matbe, Barqi Press, Delhi, 1921 AD] refers to a formulation containing *Mucuna pruriens* Linn, *Myristica fragrans* Houtt, *Tribulus terrestris* Linn, *Curculigo orchiodides* Gaertn, and *Anacyclus pyrethrum* along with few other ingredients used as aphrodisiac.

(xiv) Name of formulation- Musalipaka; formulation ID- VS/594 [published in Rasatantrasara Evam Siddhaprayogasangrah part II; Krishna Gopal Ayurveda Bhawan; edn. 8th, 1990 (this book contains back references from 1000 B.C. to 20th century)] refers to a formulation containing *Mucuna pruriens* Linn, *Myristica fragrans* Houtt, *Tribulus terrestris* Linn, *Withania somnifera* and *Anacyclus pyrethrum* along with few other ingredients used as aphrodisiac and for the treatment of impotency.

(xv) Name of formulation- Brihat Musalipak; formulation ID- BD/07 [published in Yogacintamani/Sarasangraha, translated by Dattaram Caube, Khemraj Srikrishnadas, Srivyanakeshwar press, Mumbai, edn. Nov, 2006, page 25-27] refers to a formulation containing *Mucuna pruriens* Linn, *Myristica fragrans* Houtt, *Tribulus terrestris* Linn, *Withania somnifera* and *Anacyclus pyrethrum* along with few other ingredients used as aphrodisiac and for the treatment of impotency.

D2: WO2006111830 A2 discloses an herbal formulation comprising the synergistic combination of fiber/powder/granules of the aerial parts of at least two plants selected from the group comprising *Marticaria chamomilla*, *Hygrophila auriculata*, *Aquilaria agallocha*, *Valeriana wallichii*, *Nordostachys jatamansi*, *Artemisia pallens*, *Papaver somniferum* (mainly leaf), *Evolvulus alsinoides*, *Ficus benghalensis*, *Echinops echinatus*, *Lobelia nicotianifolia*, *Mucuna pruriens*, *Tribulus terrestris* and along with one or more flavoring agents selected from essential/aromatic oils.

D3: 811/MUM/2006 discloses a herbal composition for the treatment of oligospermia and to increase the sperm motility in mammals, comprising 500 mg mixture of herbs in a hard gelatin Capsule, which comprises: alcoholic extracts of A) *Withania somnifera*, 75 to 150 mg; B) *Pueraria tuberosa*, 40 to 70 mg; C) *Asparagus racemosus*, 50 to 100 mg; D) *Mucuna pruriens*, 120 to 175 mg; E) *Tribulus terrestris*, 20 to 60 mg; F) *Trychospermum ammi*, 20 to 50 mg; and G) *Chlorophytum arundinaceum*, 40 to 100 mg, and powdered of A) *Styrax officinale*, 25 to 30 mg; B) *Crocus sativus*, 5 to 10 mg; and C) *Myristica fragrans*, 25 to 75 mg.

D4: 1651/CHE/2006 discloses an ayurvedic medical preparation named "MUSLIPOWER X-TRA" where in the chemical constituents such as alkaloids, minerals and protein extracts of 1. *Chlorophytum borivillianum* (safed musli) 2. *Mucuna purita* (kapikachu) 3. *Muringa Oleifera* (siguru) 4. *Withania Somnifera* (Aswagandha) 5. *embilica officinalis* (Amalaki/Phyllanthus emblica) 6. *Tribulus Terrestris* (njerinjil) 7. *Hygrophila auriculata* (vayalchully) 8. *Myristica* (jathika) are extracted in a unique manner and are mixed at a particular quantity to obtain this unique ayurvedic medicine that is used for male and female sexual inadequacies.

D5: RO117897 (B1) discloses a revitalizing Ayurveda supplement for males comprises 80 g of *Asparagus racemosus* (sin A javanicus); 90 g *Asphaltum* (shilajit); 60 g of *Boerhavia diffusa*; 70 g of *Centipeda minima*; 10 g of *Cinnamomi cortex* (cinnamon); 30 g of *Chlorophytum arundinaceum*; 20 g of *Corallium rubrum* (Coral Bhasm); 10 g of *Elletaria cardamomum*; 100 g of *Gummi accacia*; 10 g of

Mesua ferrea; 80 g of Mucuna prurita; 10 g of Miristica fragrans; 40 g of Spheranthus indicus; 120 g of Sida cordifolia; 70 g of Strichnos potatorum; 80 g of Tribulus terrestris; 10 g of Piper longum; 20 g of Zinci carbonas and 20 g of Zingiber officinale. All these components, as powder, are mixed, homogenized and processed as uncoated tablets of 500 mg.

The cited documents D1-D5 disclose all the plants, independently or in combination with each other, which are present in claimed herbal formulation along with their use as aphrodisiac and in the treatment of impotency.

As per guiding principle-2 of 'Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material' issued by CGPDTM if 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 and as per guiding principle-6 of said guidelines 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). In the light of said principles claimed invention lacks inventive step as it is obvious for a person skilled in the art to combine the claimed plant parts each of which is traditionally known, either independently or in combination with each other as an aphrodisiac (as evident from the cited documents). Further as per guiding principle 4 of above said guidelines- discovering the optimum or workable ranges of traditionally known ingredients by routine experimentation is not inventive. In case of present invention the claimed optimum or workable range of ingredients (claims 5-6) cannot be considered to be inventive since the selection of optimum or workable range from already known ranges of the ingredients in the disclosed formulations (see D1-D5) is well within the expectation of a person skilled in the art.

(i) Claims 1-15 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 aggregation or duplication of traditionally known medicinal property, i.e. use as aphrodisiac, of *Mucuna pruriens*, *Tribulus terrestris*, *Myristica fragrans*, *Withania somnifera*, *Anacyclus pyrethrum*, *Astercantha longifolia* and *Curculigo orchioides* independently or in combination with each other.

3

(ii) Claims 1-15 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 and process of mere admixing of such components with no synergistic effect in such an admixture.

(iii) Claim-14 falls within the scope of such clause (d) of section 3 of Indian Patents Act as claimed process is mere use of known/conventional process for preparation of plant extracts.

4 (i) Claim-1 does not sufficiently define the invention w.r.t. the expression "pharmaceutically effective amount of extracts", the amount of each ingredient of the composition should be clearly defined alongwith the definition of the extract used.

(ii) Claims 2,3 and 5-6 goes beyond the scope of claim-1 as said claims include dried powder plant parts as part of the herbal composition whereas claim-1 only includes extract of plants in claimed composition.

5 Claim-15 cannot be allowed as per section 10(4)(c) of the Indian Patents Act as such claim is unclear, vague and unsearchable.

6 Claim-1 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 whole breadth of the claims. The examples disclose limited number of plants and limited range of the amount of plant extract used in the claimed formulation. Hence it is not reasonable to presume the existence of claimed herbal formulation over the whole breadth of the claims and to consider that all of them will show the claimed pharmacological effect.

7 Executed form I can not be taken on record as same not filed within prescribed time.

8 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 .

9 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.

10 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 28/09/2015.

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
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