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1927/KOLNP/2010

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To,
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SUB : Examination Report

APPLICATION NUMBER : 1927/KOLNP/2010
DATE OF FILING : 26/05/2010
DATE OF REQUEST FOR EXAMINATION : 10/06/2010
DATE OF PUBLICATION : 10/09/2010

a) With reference to the RQ No. 2605/RQ-KOL/2010 Dated 10/06/2010 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

b) Objections :

1 Claim 1-27 falls within the scope of section 3(p), 3(j), 3(e) and 3(d) of the Act.

The present application is considered to involve the following separate groups of inventions and raise the issue of plurality u/s 10(5) of the Act: a)

2 Claims 1-6 Ginseng + liquorice + pharmaceutical carrier & additive Claims 13-19 Ginsenoside+Glycyrrhizic acid b) Claims 7-12 Ginseng + liquorice + jujube+ pharmaceutical carrier & additive Claims 20-27 Ginsenoside+Glycyrrhizic acid+ jujube cAMP

The application lacks novelty and inventive step in view of the citations below. Reference is made to the following documents: 1. Mohammad Azam Khan, Ikseer Azam, Vol. I (19th century AD), Munshi Nawal Kishore, Lucknow, Fourth Edition Pg 19 Formulation ID: NA5/2-506B - Formulation Name: Sharbat-e- Unnab Bara-e- Maali Kholia 2. Mohammad Akmal Khan, Qaraabaadeen Azam wa Akmal (20th century AD), Matba Siddiqi, Delhi 1 Matba Mu stafai, Delhi, 1909 AD P 6, Formulation ID: BA3/17, Formulation Name: Itrecfal Muqawwi Dimagh 3 .Vagabhata: A taliga Hrdaya - (commentary by Arunadutta) edited by Bhisagacarya Harisastri Paradakara vaidya : Chaukhamba Orientalia aranasi, edn. 8th, 1998, [Time of origin 5th century] Pg 383, Formulation ID: RS/23/302, Formulation Name: BaJa Tail Nirupanam 4 .Vagabhata: A taliga Hrdaya - (commentary by Arunadutta) edited by Bhisagacarya Harisastri Paradakara vaidya : Chaukhamba Orientalia aranasi, edn . 8th, 1998, [Time of origin 5th cent4ry] Pg 795 formulation ID: RS23 / 1330, Formulation ID: RS23 / 1330 formulation Name: Mahabbutarava Ghrita 5. Lankapatiravala: Arkaprakasa: i - Edited and translation by Indradeva Tripathi: Krishnadas Academy, Varanasi, Edn . 1st 1995 Pg 41 Formulation ID: AK14/40A, . Formulation Name: Jalayasti Arka Gunah ID. : 6. Brhat Nighaz: Itu Ratnakara (Saligramanighantubhusanam) - Compiled by Gangavi DU Srikr z: la Dasa , Translated by Sri Dattarama rikrsnalala Mathur a; Vol. -4 (Part VII), edn. 1997, Khemaraja Srikrnsadas Prakasana, Mumbai-4 [This book contains back references from 000 B.C. to 20th century] Pg 130 Formulation ID: RS/4246 Formulation Name: Jalaya tyarkagulaaji 7. Kr Darama Bhatta: Siddhabhe ajamaljimala: i - Commentary by Kaladhara Bhatta, Chaukhamba J: rishnadas Academy, Varanasi, Edn . 3rd 2003 Pg 56 Formulation ID: RS4/167C Formulation Name: Badara Phala (pakva) 8. Mohammad Kabiruddin, Bayaaz-e-Kabir, Vol. II (Compiled), Daffar-al- Maseeh, Karol Bagh, New Delhi, 193 8 AD Pg 119 Formulation ID: MA3/ 442, Formulation Name: Arq-e- Unnab 9. Mohammad Najmul Ghani Khan: Khazaain-al-Advia, Vol. I (20th century AD), Nadeem Yunus Printer I Sheikh Mohd Basheer & Sons, Lahore, 1911 AD Pg 81-7 Formulation ID: NA2/3 841 Formulation Name: Dawa -e- Safoof Labni 10. -; Yogaratnakara: i - Commentary by Lak mipatisastri, Chaukhamba Sanskrit Sansthan, Varanasi Edn. 8th 2004 Pg 497 Formulation ID: RG8/ 1894, Formulation Name: Yasthyadi Yoga 11. Mohammad Azam Khan, Ikseer Azam, Vol. IV (19th century AD), Matba Nizami, Kanpur, 1872 AD Pg 364, Formulation ID: BA4/2158, Formulation Name: Matbookh-e- Musakkin..... 12. CN I 836 687 A (BEIJING OUNAEER BIOENGINEERING TECHNOLOGY CO LTO) 27 September 2006 (2006-09-27)/ EP1862158 A1 (EP family member) .

Exhibits 1-4 & 12 are relevant for the purpose of novelty & discussed here. Exhibit 1: (pg. no.5-8) refers to a formulation containing cultivated licorice (Glycyrrhiza glabra Linn.) and Zizyphus jujuba Linn. along with few other ingredients used for the treatment of Melancholia and Insomnia through oral administration. Exhibit 2: (pg. no.9-12) refers to a formulation containing cultivated licorice (Glycyrrhiza glabra Linn.) and Zizyphus jujuba Linn. along with few other ingredients used as Brain tonic through oral administration. Exhibit 3: (pg. no.13-18) refers to a formulation containing Zizyphus jujuba Mill. and cultivated licorice (Glycyrrhiza glabra Linn.) along with few other ingredients used for the treatment of Idiopathic psychotic syndrome and Psychosis/Insanity/Mania. Mode of administration is as directed by physician. Exhibit 4: (pg. no.19-23) refers to a formulation containing cultivated licorice (Glycyrrhiza glabra Linn.) and Zizyphus jujuba Mill. along with few other ingredients used for the treatment of Idiopathic psychotic syndrome and Psychosis/Insanity/Mania through oral administration. The instant application claims the usefulness of a herbal composition comprising ginseng, liquorice and jujuba for treating an anxiety disorder. However prior art 1-4 disclose cultivated licorice (Glycyrrhiza glabra Linn.) and Zizyphus jujuba Linn. have been used for the treatment of Melancholia, Insomnia, Idiopathic psychotic syndrome, Psychosis/Insanity/Mania, Depression,

Psychoneurosis, Palpitation, Hallucinations and as Brain tonic and Sedative/ Anxiolytic through oral administration or as directed by physician in the Indian systems of Medicine since long. Thereby claims 1-6 of instant application lacks novelty in view of the cited prior art 1-4. Exhibit 12 discloses (cf. claims) pharmaceutical compositions comprising (i) ginseng and (ii) liquorice with or without (iii) jujuba for use in the treatment of depression, and pharmaceutical compositions comprising (i) ginsenoside from ginseng and (ii) glycyrrhizic acid and/or glycyrrhetic acid from liquorice with or without (iii) jujuba cAMP for use in the treatment of depression. The ginsenosides Rg1 and Rb1 are implicitly disclosed as present in the compositions, since the process for extracting ginsenosides from ginseng described in the present application is identical to the process described in 12 (ethanol extraction

followed by chromatography). It discloses a method for preparing jujuba cAMP by extracting jujuba in ethanol followed by chromatography which is generally known as a concentration step similar to instant application. Thereby claims 1-31 of instant application lacks novelty in view of exhibit 12.

The subject-matter of claims 1-12 of the present application cannot be considered to involve an inventive step u/s 2(1)(ja) in view of the citation exhibits 1-12. In addition to exhibits 1-4 and 12 discussed for novelty & relevant here, the exhibits 5-11 are relevant here Exhibit 5:(pg. no.24-25) refers to a formulation containing cultivated licorice (Glycyrrhiza glabra Linn.) as a single ingredient used for the treatment of Depression through oral administration. Exhibit 6:(pg. no.26-27) refers to a formulation containing cultivated licorice(Glycyrrhiza glabra Linn.) as a single ingredient used for the treatment of Depression. Mode of administration is as directed by physician. Exhibit 7:(pg. no.28-29) refers to a formulation containing Zizyphus jujuba Mill. as a single ingredient used for the treatment of Psychoneurosis. Mode of administration is as directed by physician. Exhibit 8:(pg. no.30-31) refers to a formulation containing Zizyphus jujuba Linn. along with one other ingredient used as Brain tonic through oral administration. Exhibit 9:(pg. no.32-34) refers to a formulation containing cultivated licorice(Glycyrrhiza glabra Linn.) along with few other ingredients used for the treatment of Palpitation, Depression and Hallucinations through oral administration. Exhibit 10:(pg. no.35-37) refers to a formulation containing cultivated licorice (Glycyrrhiza glabra Linn.) along with few other ingredients used for the treatment of psychosis/Insanity/Mania through oral administration. Exhibit 11: (pg. no.38-39) refers to a formulation containing Zizyphus jujuba Linn. Along with few other ingredients used as Sedative/ Anxiolytic through oral administration. The exhibits 1-4, 12 straight forwardly direct the person skilled towards the instant application. The only difference between exhibit 12 & the composition in instant application is for use in the treatment of anxiety and not depression. A skilled person would be motivated to reach the instant application with exhibit 12 alone or in combination with the other exhibits 1-4 cited herein. Cited exhibits 5, 6 refer to use of liquorice alone, Cited prior art 7 refer to use of jujube alone, and prior art 8, 11 refer to use of jujube with other ingredients and similarly prior art 9, 10 refer to usage of liquorice with other ingredients to treat psychosis, insanity & mania. Exhibits 5-11 alone or in combo with exhibit 12 and or exhibits 1-4 would provide the skilled person motivation to work around to reach the instant application.

6 Composition claims need to incorporate all ingredients and their percentages.

7 Method Claims 28-31 lack clarity & disclosure need to include technical parameters, ie, physical & chemical parameters.

The subject-matter of claims 28-31 does not fulfil the clarity & disclosure requirements of sec 10(4) of Act, since it is not known what type of

8 chromatography column is meant by the term "a macroporous resin bound with an aldehyde group", "OU-2 macroporous resin" and "ME-2 macroporous resin".

9 Biological materials has been used in the invention ie, ginseng, liquorice and jujube. Therefore the source/geographical origin should be specified in the specification & if the origin is in India, NBA approval is required. If it's 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 materials used in the invention is not from India and should clearly specify the country of source & geographical origin of the same

In page 4 lines 20, 25-8 and page 5 lines 1-2 explicitly mention that Ginseng, liquorice & jujube when normally decocted & extracted do not show

10 significant anti-anxiety effect & it's only on further purification & concentration of the effective components that the significant effect is obtained.

Thereby according to applicant own disclosure only claims 20-27 display significant effect.

11 PA and Proof of right needs to be filed with petition

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, 12 in respect of same or substantially the same invention filed in all countries out side India, 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 invention should be 13 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.

14 Fresh form 3, 5 needs to be filed with the application number duly mentioned.

15 Verified English translation of priority document needs to be submitted along with petition.

16 Preamble to drawings needs to be filed in the prescribed manner.

17 Title needs to be made consistent with amended description and claims u/r 13(7)(a).

18 Typographical error in pg 31, claim 28 (a)?? extrac? needs to be rectified.

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,

19 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 invention should be

20 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 06/02/2015.

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.

(Dr. Susil Kumar Mitra)

Asst. Controller of Patents & Designs

NOTE : All Communications to be sent to the Controller of Patents at INTELLECTUAL PROPERTY BUILDING Sector V, Salt Lake City
Kolkata-700091.