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**Letter No.:-CIEM/2013/**

**Date : 23/07/2013**

To,  
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Advocates, Patent  
& Trade Mark Attorneys.  
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**SUB : Examination Report**

APPLICATION NUMBER : 7124/DELNP/2008  
DATE OF FILING : 21/08/2008  
DATE OF REQUEST FOR  
EXAMINATION : 04/02/2009  
DATE OF PUBLICATION : 03/10/2008

With reference to the RQ No. 970/RQ-DEI./2009 Dated 04/02/2009 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 :**

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

**D1: WO01/15553 A1** discloses a method of treating an inflammatory response, which may include allergic rash, in an animal by administering to the animal a composition (fruit extract) which has anti-inflammatory activity (see e.g. claim 19). It discloses compositions containing fruit extracts comprising anthocyanidines such as cyanidine glycoside and pelargonidin and their use in the preparation of a medicament or food supplement for the treatment of amongst others allergic rash and asthma (page 2, lines 26-33; page 3, lines 1-10; Page 11, lines 13-19; claims 20, 21 ). D1 further teaches that the anti-inflammatory activity of the extract is mediated by pelargonidin (see e.g. page 3, lines 1-14).

1 **D2: WO 00/33824 A** discloses the use of anthocyanins extracted from cherries such as amongst others cyanidin-3-glycoside (see Fig 1) for the preparation of a medicament for the treatment of inflammatory diseases such as allergic rash and asthma (page 4, lines 9-16; page 5, lines 1-7).

**D3: Gabor Miklos et al: "Effect of benzopyrone derivatives on simultaneously induced croton oil ear edema and carrageenan paw edema in rats" Acta Physiologica Hungarica, Budapest, HU, vol. 77, no. 3-4, 1 January 1991 (1991-01-01), pages 197-207** discloses a study showing the effect of pelargonidin chloride on the reduction of carageen in paw oedema and croton oil ear oedema in rats (page 201, lines 5-8 and Table VI).

**D4: KIM HYUNG-MIN ET AL: "The evaluation of the antianaphylactic effect of Oryza sativa L. subsp. hsien Ting in rats" 1 July 1999 (1999-07-01), PHARMACOLOGICAL RESEARCH, ACADEMIC PRESS, LONDON, GB, PAGE(S) 31 - 36** discloses the antianaphylactic

effects of black rice extracts compositions (abstract, page 35, right column, line 32-page 36, left column, line 3).

**D5: JP 2002 338842 A** discloses a pigment formulation for food colouring containing pelargonidin, phycocyanin and proanthocyanin.

**D6: JP 06 271850 A** discloses the extraction of cyanidin-glycoside from amongst others black rice for use as an anti-oxidant in foodstuffs and pharmaceuticals.

**D7: WO 03/074067 A** discloses berry extracts containing pelargonidin and cyanidin for the preparation of a medicament for the treatment of amongst others asthma and pulmonary diseases (page 4, lines 8-15; page 17, line 26-page 18, line 14).

**D8: Formulations retrieved from Traditional Knowledge Digital Library ?**

**1. Formulation name: Kumkuma Sali Guna [formulation ID: RS8/1048]** published in Pandita Narahari, Rajanighantau - Edited with Hindi Commentary by Indradeo Tripathi, Krishnadas Academy, Varanasi, Edn. 2nd 1998 Pg 537 refers to a formulation containing Rice, Paddy (*Oryza sativa* Linn.) as a single ingredient used for the treatment of Acute diarrhoea. Mode of administration is as directed by physician.

**2. Formulation name: Kalamasali Gunaah [formulation ID: RS6/611]** published in Kaiyadeva; Kaiyadevanighantau - (Pathyapathyavibodhakah) Edited and translated by P.V. Sharma and Guru Prasad Sharma, Chaukhamba Orientalia, Varanasi, Edn. 1st, 1979 Pg 303 refers to a formulation containing Rice, Paddy (*Oryza sativa* Linn.) as a single ingredient used for the treatment of Cough / Bronchitis and acute diarrhoea. Mode of administration is as directed by physician.

**3. Form name: Chawal Barae Surfa Wa Humma [formulation ID: MH 4/116B]** published in Mohammad Azam Khan; Muheet-e-Azam Vol II (Part I) (19th century AD), Matba Nizami, Kanpur, 1895 AD Pg 57 refers to a formulation containing Rice, Paddy (*Oryza sativa* Linn.) as a single ingredient used for the treatment of Cough / Bronchitis through oral administration.

**4. Formulation name: Joshaanda Bara-e- Waja-ul- Medah [formulation ID: JA6/579F]** published in Mohammad Najmul Ghani Khan; Khazaain-al-Advia, Vol III (20th century AD), Nadeem Yunus Printer Sheikh Mohd Basheer & Sons, Lahore, 1926 AD Pg 592 refers to a formulation containing Rice, Paddy (*Oryza sativa* Linn.) along with one other ingredient used for the treatment of Gastritis through oral administration.

**5. Formulation name: Dawa Bara-e- Niswar [formulation ID: NA3/1245]** published in Kareem Bakhsh; Miftaah-al-Khazaain (20th century AD), Dar-al- Kutub Rafeeq-al- Atibba wal Hakeem, Lahore, 1930 AD Pg 561 refers to a formulation containing Rice, Paddy (*Oryza sativa* Linn.) along with one other ingredient used for the treatment of Conjunctivitis through oral administration.

**6. Formulation name: Zaroor-e-qula-e-surkh-3 [formulation ID: NA4/2127]** published in Mohammad Najmul Ghani Khan; Qaraabaadeen Najm-al-Ghani (20th century AD), Munshi Nawal Kishore, Lucknow, (Second Edition) 1928 AD Pg 353 refers to a formulation containing Rice, Paddy (*Oryza sativa* Linn.) along with few other ingredients used for the treatment of all types of Stomatitis of Children through local application.

**7. Formulation name: Mastu Haritaki Yoga [formulation ID: RS14/351B]** published in Kafi Dasa; Vaidyamanorama; - with Hindi translation - Central Council for Research in Ayurveda & Siddha, Govt. of India, New Delhi, Edn. 2005 [Time of origin 13th century] Pg 87 refers to a formulation containing Rice, Paddy (*Oryza sativa* Linn.) along with few other ingredients used for the treatment of Ophthalmia neonatorum or Acute conjunctivitis of infants through local application.

**8. Formulation name: Majoon Barmaki [formulation ID: MH5/942]** published in Mohammad Akbar Arzani; Qaraabaadeen Qaadri (17th century AD), Ahmadi Publication, Delhi, 1968 AD Pg 134 refers to a formulation containing Rice, Paddy (*Oryza sativa* Linn.) along with few other ingredients used for the treatment of Bronchial asthma due to Cough/Bronchitis through oral administration.

**9. Formulation name: Sitapitte Udvartana [formulation ID: AK9/987]** published in Cudamani; Rasakamadheni Samhita - Edited by Jivaramakaladasa Sastri, Part 4, Chaukhamba Publishers, Varanasi, Edn. 1st 1992 Pg 322 refers to a formulation containing Rice, Paddy (*Oryza sativa* Linn.) along with one other ingredient used for the treatment of Urticaria through local application.

**10. Formulation name: Sitapittapathyah [formulation ID: SL/348]** published in Brhat Nighantu Ratnakara - Compiled by Gangavisnu Srikrna Dasa, Translated by Sri Dattarama Srikrnalala Mathura; Vol-3 (Part VI), edn. 1996, Khemaraja Srikrnadas Prakasana, Mumbai-4 [This book contains back references from 1000 B.C. to 20th century] Pg 1315 refers to a formulation containing Rice, Paddy (*Oryza sativa* Linn.) along with few other ingredient used for the treatment of Urticaria, Urticaria/ Allergic rashes, Erythema/ a type of urticaria through oral administration.

**11. Formulation name: Habb Bara-e- Surfa Ratubi [formulation ID: MH1/1294]** published in Mohammad Shareef Khan; Haaj-al-Amraaz (18th century AD), Afzal-al- Matabe, Barqi Press, Delhi, 1921 AD page 104 refers to a formulation containing Rice, Paddy (*Oryza sativa* Linn.) along with few other ingredient used for the treatment of Cough/ Bronchitis, Phlegmatic Cough and Bronchial asthma through oral administration.

**12. Formulation name: Madhukadi Hima [formulation ID: RS 22/942]** published in Ayurveda Sarasamgrahah - Shri Baidyanath Ayurveda Bhavan Limited, Calcutta, Edn. 2003 page 715 refers to a formulation containing Rice, Paddy (*Oryza sativa* Linn.) along with few other ingredients used for the treatment of Rhinitis through oral administration.

**13. Formulation name: Zaroor Bara-e- Qulaa-e- Dahan [formulation ID: MH1/984]** published in Mohammad Shareef Khan; Haaj-al-Amraaz (18th century AD), Afzal-al- Matabe, Barqi Press, Delhi, 1921 AD Pg 85 refers to a formulation containing Rice, Paddy (*Oryza sativa* Linn.) along with few other ingredient used for the treatment of Stomatitis. Mode of administration is as directed by physician.

**14. Formulation name: Chawal Barae Surfa Wa Humma [formulation ID: MH4/116B]** published in Mohammad Azam Khan; Muheet-e-Azam Vol. II (Part I) (19th century AD), Matba Nizami, Kanpur, 1895 AD Pg 57 refers to a formulation containing Rice, Paddy (*Oryza sativa* Linn.) along with few other ingredient used for the treatment of Cough/ Bronchitis, Angina pectoris through oral administration.

Both the compounds pelargonidin and cyaniding glycoside are well known in prior art and their use in treatment of asthma and allergic diseases is also disclosed in the cited documents hence the claims lack novelty as composition prepared by the known compounds extracted from a new source and using them for treatment of known diseases cannot be considered novel. In view of the cited documents D1-D8 it is obvious for a person skilled in the art to use the teachings of said documents along with the traditionally known properties of the *Oryza sativa*, which is known for the treatment of allergic diseases, so the use of the active component of said plant independently or in combination cannot be considered as inventive.

(i) Claims 1-3 fall within the scope of such clause (p) of section 3 of Indian Patents Act as the claimed invention relates to mere use of active component of *Oryza sativa* whose medicinal properties were well known and prior used as part of teachings of traditional knowledge.

2

(ii) Claims 1-3 fall within the scope of such clause (e) of section 3 of Indian Patents Act as claimed composition appears to be mere admixture of the claimed components with no synergistic effect.

3

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

4

Claims 1-3 do not sufficiently define the invention w.r.t. the constituents of the claimed composition as claim-1 does not define the pharmaceutical composition and claims 2-3 defines only a single component of the claimed composition.

5

Each claim 1 (relating to pharmaceutical composition for preventing or treating bronchial asthma comprising black rice extract), 2 (relating to pharmaceutical composition for preventing or treating bronchial asthma comprising pelargonidin) and 3 (relating to pharmaceutical composition for preventing or treating bronchial asthma comprising cyanidin glycoside (cyanidin 3-O-p-glucopyranoside)) relates to an independent invention.

6 Clearly disclose the source and geographical origin of the biological material (black rice) from which compounds and extract 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.

7 Claims 1-3 of instant patent application conflict with claim-10 of parent application 4468/DEL.NP/2005.

8 The Drawings referred to in the specification should be prepared in accordance with the instructions contained in the Rule 15 of the Patent Rules, 2003(as amended in 2006).

9 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 .

10 Extraneous matter like title from page 2, PCT application details on pages of complete specification etc. should be deleted and fresh retyped pages should be filed.

11 Pages of the complete specification should be renumbered.

12 A duly verified copy of English translation of the international patent application should be filed as per rule 20(3)(b) of the Patent Rules 2003.

13 The present application is not a valid application u/s 16 as it is not complying with the requirements of sub section (1) and (3) of section 16.

14 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.

15 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 you application will be treated as "Deemed to have been abandoned" under section 21(1) of the Act. The last Date is 23/07/2014.

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)**

Asst. 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.**