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1109/CHE/2010

Date : 17/03/2014

Letter No.: -BIO-TECH/2014/

To,
DR. A.N. SINGH,
M/S. CELESTIAL BIOLABS LTD,
PLOT NO.231-A, ROAD NO.12, MLA COLONY,
BANJARA HILLS, HYDERABAD - 500 034,
ANDHRA PRADESH.

SUB : Examination Report

APPLICATION NUMBER : 1109/CHE/2010
DATE OF FILING : 20/04/2010
DATE OF REQUEST FOR EXAMINATION : 20/04/2010
DATE OF PUBLICATION : 28/10/2011

3) With reference to the RQ No. 2732/RQ-CHE/2010 Dated 20/04/2010 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 :

Claim 1 is not patentable u/S 3(i) of the Patents Act, 1970 as it relates to traditional knowledge. Apium graveolens Linn, Syzygium aromaticum, Amomum subulatum, Elettaria cardamomum, Acorus calamus, Piper nigrum, Piper longum, Zingiber officinale, Puffed sugar drops have been used for the treatment of Weakness of Stomach, Dyspepsia/Loss of appetite, Colic of abdomen, Nausea, Gastric dyscrasia, Gastralgia, Flatulence, diseases of abdomen, indigestion and used as Digestive, Stomachic, Appetizer, carminative and Laxative through oral administration in the Indian systems of Medicine.

Refer enclosed TKDL documents D1: Mohammad Shareef Khan; Ilaaj-al-Amraaz (18th century AD), Afzal-al-Matabe, Barqi Press, Delhi, 1921 AD Pg. 159 Formulation ID: MH 1 / 1856. Formulation Name: Ramehnan.

D2: Mahendra Bhaugika; Dhanvantarinighantauh - Edited by P.V.Sharma; Translated by- Guru Prasad Sharma; Chaukhambha Orientalia, Varanasi, Edn. 3rd, 2002, Pg 261 Formulation ID: AK12/701 Formulation Name: Trikatu Guna.

D3: Mohammad Akbar Arzani; Qaraabaadeen Qadri (17th century AD), Ahmadi Publication, Delhi, 1968 AD, Pg 186 Formulation ID: MHIS/1263 Formulation Name: Sharbat-e- Macbah.

D4: Mohammad Akbar Arzani; Qaraabaadeen Qadri (17th century AD), Ahmadi Publication, Delhi, 1968 AD, Pg 172 Formulation ID: MHIS/ 1 156 Formulation Name: Dawa-e-dard-e- Me Da.

D5: Mohammad Najmul Ghani Khan; Qaraabaadeen Najm-al-Ghani (20th century AD), Munshi Nawal Kishore, Lucknow, (Second Edition) 1928 AD, Pg 703, Formulation ID: NAF/4551 Formulation Name: Majoon Muqawwi.

D6: Rasatantrasarah Evam Siddhaprayogasangraha:- part 11; Krishan Gopal Ayurveda Bhawan; Edn 8th, 1990. [This book contains back references from 1000 B.C to 20th century], Pg 397.

D7: Mohammad Shareef Khan; Ilaaj-al-Amraaz (18th century AD), Afzal-al-Matabe, Barqi Press, Delhi, 1921 AD, Pg 154 Formulation ID: MH 1/1801 Formulation Name: Jawarish Naamushk- Mushil Formulation ID: RS21 /471 Formulation Name: Hapusadieuma.

2 Claim 1 is not patentable u/S 3(e) of the Act as it relates to a mere admixture lacking support in the description for synergistic activity between the constituents.

Notwithstanding above mentioned objections, Claim 1 lacks inventive step u/S 2(1)(ja) in view of cited prior art documents. D1: (pg. no. 04-09) refers to a formulation containing Apium graveolens Linn, Syzygium aromaticum, Elettaria cardamomum, Amomum subulatum, Acorus calamus, Piper nigrum, Piper longum, Zingiber officinale, Puffed sugar drop along with few other ingredients used for the treatment of Weakness of Stomach through oral administration.

D2: (pg. no. 10-11) refers to a formulation containing Zingiber officinale Roscoe, Piper nigrum Linn., Piper longum Linn. along with few other ingredients used for the treatment of Dyspepsia/Loss of appetite and Colic of abdomen through oral administration.

D3: (pg. no. 12-14) refers to a formulation containing Piper nigrum Linn., Piper longum, Zingiber officinale Roscoe, Elettaria cardamomum (Linn.), Amomum subulatum along with few other ingredients used as Stomachic, Digestive and used for the treatment of Diarrhoea, Nausea and Gastric dyscrasia through oral administration.

D4: (pg. no. 15-17) refers to a formulation containing Zingiber officinale Roscoe, Piper nigrum Linn., Piper longum Linn., Apium graveolens Linn along with few other ingredients used for the treatment of Gastralgia, Flatulence and indigestion through oral administration.

D5: (pg. no. 18-20) refers to a formulation containing Zingiber officinale Roscoe and Apium graveolens along with few other ingredients used as Stomachic, Appetizer, carminative and used for the treatment of Dyspepsia/Loss of appetite through oral administration.

D6: (pg. no. 21-24) refers to a formulation containing Piper nigrum Linn., Acorus calamus Linn. and Piper longum along with few other ingredient used as Laxative, Appetizer and used for the treatment of Diseases of abdomen, Dyspepsia/Loss of appetite and Indigestion through oral administration.

D7: (pg. no. 25-27) refers to a formulation containing Zingiber officinale Roscoe, Piper nigrum, Piper longum, Elettaria cardamomum, Granular sugar along with few other ingredients used as Laxative, carminative and for the treatment of colic through oral administration. Apium graveolens Linn.

Syzygium aromaticum, Amomum subulatum, Elettaria cardamomum, Acorus calamus; Piper nigrum, Piper longum, Zingiber officinale. Puffed sugar drops have been used for the treatment of Weakness of Stomach, Dyspepsia/Loss of appetite, Colic of abdomen, Nausea, Gastric dyscrasia, Gastralgia, Flatulence, diseases of abdomen, indigestion and used as Digestive, Stomachic, Appetizer, carminative and Laxative through oral administration in the Indian systems of Medicine, since long, as is evident from exhibits cited from the books namely, Ilaaj-al-Amraaz by Mohammad Shareef Khan (Unani, D1: pg.no. 04-09), Dhanvantarinighantauh by Mahendra Bhaugika (Ayurveda, D2: pg. no. 10-11), Qaraabaadeen Qaadri by Mohammad Akbar Arzani (Unani, D3: pg. no. 12-14), Qaraabaadeen Qaadri by Mohammad Akbar Arzani (Unani, D4: pg. no.15-17), Qaraabaadeen Najm-al-Ghani by Mohammad Najmul Ghani Khan (Unani, D 5: pg. no. 18-20), Rasatantrasarah Evam Siddhaprayogasamgrahah part II (Ayurveda, D6: pg. no. 21-24) and Ilaaj-al-Amraaz by Mohammad Shareef Khan (Unani, D7: pg. no. 25-27).

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. Therefore, such claims cannot be considered inventive. In this regard, it would normally be expected that such combinations of medicinal plants would be more effective than each of the medicinal plants when applied separately (additive effect).

4 Claim 1 is not fully supported by the description, with working example for claimed mixture and its preparation, as required u/s 10(5) of the Patents Act, 1970.

5 Complete specification should fully and particularly describe the invention and its operation and use and the method by which it is to be performed. The complete specification should also disclose the best method of performing the invention known to the applicant and for which he is entitled to claim protection, as required U/S.10(4) of the Patents Act, 1970.

6 Attention of the applicant is invited towards Section 6 of Biodiversity Act, 2002 which mandates that if biological material procured from India is used in an application for patent, permission and other information for making application for patent should be obtained from the National Biodiversity Authority, Relevant application form (Form 3, Rule 18) for such permission is available in website of National Biodiversity Authority, Form 1 of Patent Act should be completed w.r.t column 9 (iii).

Source and geographical origin of the biological material used should be given in the specification in accordance with section 10(4)(d) of the Act.

7 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.

8 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 17/03/2015.

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. Sharana Gouda)

Asst. Controller of Patents & Designs

NOTE : All Communications to be sent to the Controller of Patents at INTELLECTUAL PROPERTY BUILDING G.S.T. Road, Guindy Chennai-600032.

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