

1512/MUM/2011



GOVERNMENT OF INDIA
PATENT OFFICE
INTELLECTUAL PROPERTY BUILDING
Near Antop Hill Post Office, S.M.Road, Antop Hill
Mumbai - 400 037

Tel No. (091)(022) 24137701,
24141026, 24150381, 24148165,
24171457
Fax No. 022 24130387
E-mail : mumbai-patent@nic.in
Web Site : www.ipindia.nic.in



Date : 26/12/2013

Letter No.:-CHEM/2014/

To,
HIRAL CHANDRAKANT JOSHI
CHANDRAKANT M. JOSHI
PATENT & TRADE MARK ATTORNEYS,
5TH & 6TH FLOOR "VISHWANANAK",
CHAKALA ROAD, ANDHERI (EAST),
MUMBAI- 400 099.

SUB : **Examination Report**

APPLICATION NUMBER : 1512/MUM/2011
DATE OF FILING : 18/05/2011
DATE OF REQUEST FOR EXAMINATION : 18/05/2011
DATE OF PUBLICATION : 08/07/2011

With reference to the RQ No. 1720/RQ-MUM/2011 Dated 18/05/2011 in the above mentioned application for Grant of Patent ,
a) Examination has been conducted under Section 12 and 13 of the Patents Act 1970 , The following objections are hereby
communicated

b) Objections :

Reference is made to following documents:

D1: ?Validated HPLC_UV method for the determination of berberine in raw herb (Berberis aristata DC), its extract and in
commercially marketed Ayurvedic forms?

- 1 Subject-matter claimed in claim 1 is not meeting requirement of section 2 (1) (j) of Patents Act being obvious over document D1;
Document D1 discloses Berberis aristata as plant material being used for extraction for curing piles, thus use of powder of the
Berberis aristata along with kalmi soda, libodi is without technical advancement , thus in absence of technical effect achieved due
to the modification over D1 , no inventive step may be acknowledged;
- 2 Subject-matter claimed in claim 1 is not patentable u/s 3 (e) of Patents act;

3 Subject-matter claimed in claim 1 is not patentable u/s 3 (p) of Patents act. Your attention has been drawn to the pregrant opposition filed under section 25(1) of the Act in this application. Exhibit 1:(pg. no. 05-06) refers to a formulation containing Rasaut (Berberis aristata) and Limbodi (Azadirachta indica) for the treatment of Piles / Ano rectal mass / Haemorrhoids through oral administration. Exhibit 2:(pg. no. 07-09) refers to a formulation containing Rasaut (Berberis aristata), Limbodi (Azadirachta indica) along with few other ingredients used for the treatment of Bleeding piles through oral administration. Exhibit 3:(pg. no. 10-11) refers to a formulation containing Rasaut (Berberis aristata), Limbodi (Azadirachta indica) along with few other ingredients used for the treatment of Severe Hemorrhage associated with Piles / Ano rectal mass / Haemorrhoids through oral administration. Exhibit 4-(pg. no. 12-13) refers to a formulation containing Rasaut (Berberis aristata), Limbodi (Azadirachta indica) along with few other ingredients used for the treatment of Pain associated with Piles I Ano rectal mass I Haemorrhoids through oral administration. Exhibit 5:(pg. no. 14-16) refers to a formulation containing Rasaut (Berberis aristata), Limbodi (Azadirachta indica) along with few other ingredients used for the treatment of Bleeding piles and Non Bleeding Piles through oral administration. Exhibit 6:(pg. no. 17-19) refers to a formulation containing Rasaut (Berberis aristata), Limbodi (Azadirachta indica) along with few other ingredients used for the treatment of Piles / Ano rectal mass / Haemorrhoids and Non Bleeding Piles through oral administration. Exhibit 7:(pg. no. 20-22) refers to a formulation containing Rasaut (Berberis aristata), Limbodi (Azadirachta indica) along with few other ingredients used for the treatment of Bleeding piles through oral administration. Exhibit 8:(pg. no. 23-25) refers to a formulation containing Rasaut (Berberis aristata), Limbodi (Azadirachta indica) along with few other ingredients used for the treatment of Bleeding piles, Piles / Ano rectal mass / Haemorrhoids through oral administration. Exhibit 9:(pg. no. 26-27) refers to a formulation containing Kalmi Soda (Potassium nitrate), (Rasaut (Berberis aristata) along with few other ingredients used for the treatment of Bleeding piles. Mode of administration is as directed by physician. Exhibit 10:(pg. no. 28-31) refers to a formulation containing Kalmi Soda (Potassium nitrate), Limbodi (Azadirachta indica) along with few other ingredients used for the treatment of Piles / Ano rectal mass / Haemorrhoids through oral administration. The alleged patent application 1512/MUM/2011 claims the usefulness of a herbal composition comprising Rasot, Limbodi, Kalmi Soda for the treatment of piles as novel. However, Rasot (Berberis aristata), Limbodi (Azadirachta indica), Kalmi Soda (Potassium nitrate) have been used alone or in combination with few other ingredients for the treatment of Piles / Ano rectal mass/Haemorrhoids, Pain associated with Piles/Ano rectal mass I Haemorrhoids, Bleeding piles, Non Bleeding Piles, Severe Hemorrhage associated with Piles/Ano rectal mass / Haemorrhoids through oral administration in the indian systems of medicine, since long, as is evident from exhibits cited from the books namely, Siddhabhesajamanimalah by Ksnarama Bhatta (Ayurveda,Exhibit 1:pg. no. 05-06), Gadanigraha by Sodhala (Ayurveda, Exhibit 2-.pg. no. 07-09), Ilaaj-al-Amraaz by Mohammad Shareef Khan (Unani;Exhibit 3:pg. no. 10-11), Qaraabaadeen Azam wa Akmal by Mohammad Akmal Khan(Unani,Exhibit 4:pg. no. 12-13), Qaraabaadeen Najm-al-Ghani by Mohammad Najmul Ghani Khan (Unani,Exhibit 5 :pg. no. 14-16), Qaraabaadeen Azam wa Akmal by Mohammad Akmal Khan (Unani,Exhibit 6 :pg. no. 17-19), Caraka Samhita by Agnivesa (Ayurveda, Exhibit 7:pg. no. 20-22), Siddhayogasamgrahah - Compiled by Yadavji Trikamji Acharya (Ayurveda, Exhibit 8:pg. no. 23-25), Siddhabhesajamanimalah by Krsnarama Bhatta (Ayurveda, Exhibit 9:pg. no. 26-27) and Chikithsa Rathna Deepam by Kannusamy Pillai(Siddha, Exhibit 10 :pg. no. 28-31). In addition to the aforesaid references, some other references also exist in TKDL wherein Rasot (Berberis aristata, Limbodi (Azadirachta indica) Kalmi Soda (Potassium nitrate) have been used alone and in combination with few other ingredients for the treatment of above mentioned indications and actions. Hence the said application 1512MUM/2011 is not novel as per the cited prior art and does not involve any inventive step, therefore cannot qualify for the grant of patent rights. (For details refer exhibits filed with pregrant opposition)

Subject-matter claimed in claims 1-2 involves use of the biological material for the purpose of obtaining intellectual property, therefore applicant is require to obtain necessary permission from National Biodiversity Authority as per provisions of section 6 of National Biodiversity Act 2002;

Subject-matter claimed in claim 1-2 uses biological materials in the form of herbal extract derived from plant material for which geographical location of the same is to be disclosed in the specification as per requirement of section 10 (4) (d) 2 (D) of Patents Act 1970;

Requirement of declaration made under para 9 (3) of the Form 1 of patent application is not fulfilled,

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.

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.

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 26/12/2014.

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.

(A T Patre)

Deputy Controller of Patents & Designs