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To,
Anand & Anand Advocates
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SUB : Examination Report

APPLICATION NUMBER : 5208/DELNP/2008

DATE OF FILING : 17/06/2008

DATE OF REQUEST FOR EXAMINATION : 30/11/2009

DATE OF PUBLICATION : 26-09-2008

With reference to the RQ No. 9774/RQ-DEL/2009 Dated 30/11/2009 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 :

- 1 Title should be given in the abstract
- 2 The expression "according to claim" as used in claims should be replaced by the expression "as claimed in"
- 3 Clearly disclose the source and geographical origin of the biological material i.e. plants parts 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
- 4 (i) Claims 1-5 fall within the scope of such clause (p) of section 3 of Indian Patents Act as claimed invention is based on use of traditionally known anti ulcer and anti gastritis property of Momordica extract (as disclosed in the cited documents)
- 4 (ii) Claims 1-5 fall within the scope of such clause (d) of section 3 of Indian Patents Act as claimed invention appears to be mere discovery of known derivative of known compound with no improvement in the therapeutic effect of such compound over the known compound
- 5 Claim-1 does not sufficiently define the invention with the term "drug" as it appears that it comprises several components with Momordica extract as one of the component
- 6 Claims 4-5 appears to relate to a distinct invention as it corresponds to a drug with momordica saponin I whereas claim corresponds to drug comprising Momordica semen extract
- 7 Botanical name of the plant should be given from which Momordica semen extract prepared should be given
- 8 Subject matter of the claims does not constitute an invention u/s 2(1) (i) as the claims lack novelty and inventive step in view of cited documents

D1: Formulations retrieved from Traditional Knowledge Digital Library:

(i) **Form name:** Zimaad-e-Tufaan [**formulation ID:** WAI/246B] published in Al Jaam'ee li-Mufradaat al-Advia wal-Aghzia, vol. I (13th century AD) Marfa Auna, Cairo, Egypt, 1871 AD, page 139 refers to a therapeutic formulation containing Momordica dioeca which is useful in the treatment of gastritis and hot swelling

(ii) **Form name:** Karavellika Kvatha [**formulation ID:** AK11/1657E] published in Vangasena, commentator Shaligram Vaisya, edited Shankar Lalji Jain, Khemraj Shukrindra Das Prakashan, Bombay, edn 1996, page 422-423 refers to a therapeutic formulation containing Momordica charantia useful in the treatment of duodenal ulcer

(iii) **Form name:** Manjistha Guna Karma [**formulation ID:** VJ/152] published in Privanghantu, Chaukhamba Surabharti Prakashana, Varanasi, edn 1st, 2004, page 71 refers to a therapeutic formulation containing Momordica charantia useful in the treatment of various diseases like ulcer

(iv) **Form name:** Karvalli Guna [**formulation ID:** RS8/40] published in Rajanghantauli, edited with hindi commentary by Indradeo Tripathi, Krishnadas Academy, Varanasi, edn 2nd, 1998, page 88 refers to a formulation containing Momordica charantia which is useful in the treatment of various diseases like non healing ulcer

(v) **Form name: Vandhyakarkoti Phalam [formulation ID: RS/204]** published in Kaiyadevanighantau⁷ edited and translated by P. V. Sharma and Guru Prasad Sharma, Chaukhamba Orientalia, Varanasi, edn. 1st 1979, page 108-109 refer to a formulation containing *Momordica charantia* which is useful in the treatment of various diseases like ulcer, wound healing etc.

(vi) **Form name: Karavellagunah [formulation ID: RS/555B]** published in Brihat Nighantu Ratnakara (containing reference from 1000 B.C. to 20th century) vol. 4 (part VII), edn. 1997, page 684 refer to a formulation containing *Momordica charantia* which is useful in the treatment of various diseases like ulcer, wound healing etc.

(vii) **Form name: Vrana Ropana Yoga [formulation ID: RG2/761A]** published in Gadanigrahah, Part-3, Chaukhamba Sanskrit Sansthan (Varanasi), edn. 3rd, 1999, page 296-297 refer to a formulation containing *Momordica charantia* which is useful in the treatment of ulcer, wound healing of vital organs.

(viii) **Form name: Bandyakarkati Arka Gunah [formulation ID: AK14/108A]** published in Arkaprakash- edited and translated by Indradeva Tripathi, Krishnadas Academy, Varanasi, edn. 1st 1995, page 55 refer to a formulation containing *Momordica charantia* which is useful in the treatment of various diseases like ulcer, wound healing etc.

D2: Gurbuz I et al., "Anti-ulcerogenic effect of *Momordica charantia* L. fruits on various ulcer models in rats", *Journal of Ethnopharmacology*, 71: 77-82 (2000) discloses that the mature fruits of *Momordica charantia* L. (Cucurbitaceae) are used externally for the rapid healing of wounds and internally for the treatment of peptic ulcers in Turkish folk medicine. D2 studies the evaluation of said activity by employing ethanol-induced ulcerogenesis model in rats. A potent and dose-dependent inhibitory activity was also observed by the administration of ethanol extract of the fruits. For the bioassay-guided fractionation, the material was first extracted with hexane and then by ethanol and both extracts were found active against the same ulcer model. Furthermore, ethanol extract of the fruits showed significant activity against HCl/PEOH induced ulcerogenesis in indomethacin-pretreated rats and diethyldithiocarbamate-induced ulcer models.

D3: N. Rai et al., "Underutilized Horticultural Crops in North Eastern Region", ENVIS Bulletin. Himalayan Ecology, vol. 13(1), 2005 pages discloses that fruits of *Momordica cochinchinensis* and *M. dioica* are used in ulcers, piles, sores and obstruction of liver and spleen.

D4: Subrata De & K.M. Parikh, "Medicinal Importance of Some Common Indian Vegetables Part I", *Ancient Science of Life*, vol. IV, No.4 April 1985, Page 232-237 discloses that the seeds of *Momordica cochinchinensis* Spreng. are useful in the treatment of ulcers, sores and obstructions of liver and spleen.

D5: Materia Medica of Ayurveda: Based on: Madanapala's Nighantu, by Vaidya Bhagwan Dash, First ed. 1991 (Reprint 1994, 2001), page 96 discloses that a variety of *Momordica cochinchinensis* (Vandhya) cleanses ulcer (vrana).

D6: Prof. Dr. Weici Tang et al., "Momordica cochinchinensis (Lour.) Spreng. and *M. grosvenori* Swingle? Chinese Drug of Plant Origin, Springer, pages 665-668, 1992 discloses that semen momordicae is the dry ripe seeds of *Momordica cochinchinensis* is officially listed in Chines Pharmacopoeia and is used for treatment of ulcer, carbuncle, anal fistula, tetter and favus by external administration. It also discloses various chemical constituents of the said plant.

D7: Vashista, P. C. (1974). *Taxonomy of Angiosperms*. P.B.M. Press, New Delhi, India discloses that *Momordica cochinchinensis* seeds are used in the treatment of ulcers, sores and obstructions of liver and spleen.

D8: Ozbakis Dengiz Gueannur et al., "Effects of *Momordica charantia* L. (Cucurbitaceae) on indomethacin-induced ulcer model in rats" *The Turkish Journal Of Gastroenterology, Turkish Society Of Gastroenterology, TR*, vol. 16, no. 2, 1 June 2005, pages 85-88 discloses the beneficial effect of the oily extracts of the whole mature fruits (including the seeds) of *Momordica charantia* L. - cucurbitaceae on gastric ulcer.

D9: Yesilada E et al., "Screening of Turkish anti-ulcerogenic folk remedies for anti-Helicobacter pylori activity" *Journal Of Ethnopharmacology*, vol. 66, no. 3, September 1999 (1999-09), pages 289-293 discloses reports on the use of aqueous and methanol extracts of *Momordica charantia* fruits in the treatment of gastric ulcer.

D10: Iwamoto M et al., "Studies on the constituents of *Momordica cochinchinensis* Spreng. I. Isolation and characterization of the seed saponins, momordica saponins I and II", *Chemical And Pharmaceutical Bulletin, Pharmaceutical Society Of Japan, Tokyo, JP*, vol. 33, no. 2, 1 January 1985 (1985-01-01), pages 464-478 discloses that *Momordica* saponin I is contained in *Momordica cochinchinensis* extract.

D11: JP410059858 discloses that methanolic extract of *Momordica cochinchinensis* is a drug composition which can be used to treat gastric ulcer. Inherently JP teaches the structure of claim 4 since the same plant is used and the same extraction method is used.

D12: JP 11302180 A discloses an antiulcer medicine containing as active ingredients (i) Momordin I and/or (ii) Momordin Ic which belong to triterpenoid saponins as a natural medicine not having a side effect and habituation and having high activity and high biological safety.

The claimed invention is obvious for a person skilled in the art to try and see whether *Momordica* saponin I possess the same pharmacological activity of the extract, which is known in prior art. Further various species for *Momordica* are traditionally known in several countries for anti-ulcer and anti-gastritis properties so using claimed extract for the same properties does not involve any inventive step.

9 The chemical structure of the compound in claim-4 and the specification is illegible.

10 Form-3 filed on 22/12/2008 cannot be taken on record as the same not filed within prescribed time limit.

11 Pages of the complete specification should be renumbered.

12 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.

13 The claim part of the complete specification should commence with phrase: "We claim".

14 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

15 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.

16 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 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.

(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 Delhi - 110 078.

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