

**The Patents (Amendment) Act, 2005  
And  
The Patents (Amendment) Rules, 2006**

In the matter of Patent Application No. 1865/DI:L/2006

Filed on 21/08/2006

In the matter of hearing held u/s 14

Central Council for Research in Unani Medicine (CCRUM), New Delhi.....The Applicant

**Present –**

Ms Mona Saini of M/s L. S. Davar & Co., New Delhi.....Agent of the applicant

Dr Usama Akram of CCRUM .....The Applicant

**Hearing u/s 14 held on 26/02/2013**

**Decision u/s 15**

1. An application for grant of patent titled, 'A novel herbal composition effective against general weakness and a process thereof' was filed on 21/08/2006 by M/s L. S. Davar & Co., New Delhi on behalf of Central Council for Research in Unani Medicine (CCRUM), New Delhi. The application claimed no priority.

2. The application was examined u/s 12 and 13 of the Patents Act, 1970 and first examination report (FER) was issued on 23/02/2011. The applicant submitted reply to FER on 06/09/2011. The application was re-examined and hearing notice was issued on 04/12/2012.

3. The main objections raised in the hearing notice are as follows -

**3.1** The claims do not constitute an invention u/s 2(1)(j) in view of the prior art documents Traditional Knowledge Digital Library (TKDL);

**3.2** The claims fall u/s 3(p) in view of TKDL documents;

**3.3** Prior approval from National Biodiversity Authority (NBA) is required;

**3.4** Further description of the source and geographical origin of the plant should be provided in the specification;

4. The final amended claims that came up for hearing are as under

**Claim 1** – A novel herbal composition effective against general weakness and a process thereof comprising 75-85 mg of Kuchla Mudabbar (*Strychnos mix-vomica* Linn), 70-85 mg of Qaranfal (*Syzgium aramaticum* Merr.), 70-85 mg of Ood Saleeb (*Paconia officinals* Linn), 70-85 mg of Darchini (*Cinnamomum seylanicum* Blume), 70-90 mg of Jauzbuwa (*Myristica fragrans* Hautt) and 75-90 mg of Bisbasa (*Myristica fragrans* Hautt).

**Claim 2** – A process for preparation of a novel herbal composition effective against general weakness comprising steps of:

- detoxification of kuchla seeds followed by pulkverization forming first part,
- pulverization of Qaranfal (*Syzgium aramaticum* Merr.), Ood Saleeb (*Paconia officinals* Linn), Darchini (*Cinnamomum seylanicum* Blume), Jauzbuwa (*Myristica fragrans* Hautt) and Bisbasa (*Myristica fragrans* Hautt) forming second part,
- mixing both parts and transferring the mixture to a kneading machine with a solution such as 10% of aqua solution of gond babool/ starch,
- drying is followed by preparation of granules, which are added with antioxidant and lubricant followed by compression.

**Claims 3 to 5** are dependent on claim 2..

5. After perusing through the submissions during hearing and all the documents, the following observations have been made --

- 5.1 The applicant submitted that the claims 1 to 5 are novel and inventive due to the following reasons –
- plant parts used in the instant claims are not used as such and standardization procedures have been employed;
  - the plant parts have been combined in a certain ratio;
  - process parameters are novel;
  - clinical results showing enhanced efficacy has been furnished;
  - permission from National Biodiversity Authority (NBA) applied for.

6. Applicant's arguments have been carefully considered but are not deemed persuasive for the reasons as under -

6.1 IPD1 (AK2/591) teaches the use of all the components of the claimed composition for treatment of general weakness. Thus the present claims lack novelty in view of the cited document.

6.2 IPD2 (AK/1186) teaches use of *Cinnamomum tamala* Nees, *Cinnamomum zeylanicum* Blume, *Myristica fragrans* Houtt, *Myristica fragrans* Houtt, *Syzygium aromaticum* (Linn.) Merr. for treatment of general weakness.

6.3 IPD3 (AK/1185) teaches the use of *Cinnamomum tamala* Nees (tejapatra, *Syzygium aromaticum* (Linn.) for the treatment of general weakness.

6.4 IPD4 (RS21/766A) teaches the use of Cinnamomum camphora (Linn.), Syzygium aromaticum (Linn.) Myristica fragrans Houtt. (jēṭṭaphala, jēṭṭipatrṭ) Seed (bṭja/ phalṭsthi), Myristica fragrans Houtt. Strychnos nuxvomica Linn. (viṭamuṭi, kṭraskara (rēja. nigha.)) for the treatment of general weakness.

6.5 IPD5 (NA4/4765) teaches Cinnamomum tamala Nees, Cinnamomum zeylanicum Blume (Daarchini), Syzygium aromaticum (Linn.) Merr. & L.M. Perry (Qaranful/Laung), Myristica fragrans Houtt., Orchis officinalis Linn. (Fantafaloon/Faawaaniya/Ood Saleeb) for the use of treatment of weakness of stomach.

6.6 The problem to be solved by the claimed composition is general weakness. All the above mentioned documents teach the use of the components singly as well as in combination for treatment of general weakness. Based on the said teachings, it would be obvious to a person skilled in the art to reach at the claimed composition to solve the given technical problem. A skilled artisan would have expected that relatively minor changes in the components would have no fundamental impact on properties of the ingredients known.

Thus no inventive step can be acknowledged for the present set of claims.

6.7 In this context, I refer to 'Guidelines for processing of patent applications relating to Traditional Knowledge and Biological materials'.

*("Guiding Principle 3: In case an ingredient is already known for the treatment of a disease, then it creates a presumption of obviousness that a combination product comprising this known active ingredient would be effective for the treatment of same disease.")*

6.8 I also refer to -

*("Guiding Principle 4: Discovering the Optimum or Workable Ranges of Traditionally known ingredients by Routine experimentation is not inventive.")*

*In case of inventions relating to selection of optimum or workable range of ingredients, this is to be borne in mind that the selection of a particular range of known ingredients is not inventive since the selection of optimum or workable range is well within the expectation of a person skilled in the art.")*

6.9 I observe that although the cited references do not specifically teach adding the ingredients in the amounts claimed by the applicant; however the references do teach the ingredients of the claimed composition. The amount of a specific ingredient in a composition that is used for a particular purpose is a result effective parameter that a person having ordinary skill in the art would routinely optimize. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. It would have been customary for an artisan of ordinary skill to determine the optimum amount of each ingredient to add in order to best achieve the desired results.

Therefore, no inventive merit can be acknowledged in the selection of ranges of particular ingredient.

**6.10** The agent submitted the clinical results which showed that by the use of the claimed composition the patients got complete relief from all symptoms. I observe that the said clinical studies do confirm the activity of the claimed composition (which is also indicated in the cited TKDL documents) but do not show any enhanced efficacy or unexpected surprising results.

Also no comparative analysis or data has been submitted by the applicant showing that the particular amounts of ingredients in combination as claimed delivers enhanced results than if used in other amounts.

Thus, in absence of some demonstration of unexpected results from the claimed composition and the specified amounts, no inventive merit can be acknowledged for the instant claims.

**6.11** In absence of any inventive feature in the claims, the said claimed composition is considered to be aggregation of known properties of traditionally known components. Therefore, the said claims fall u/s 3(p) of the Patents Act, 1970.

**6.12** I observe that the process steps as claimed in claims 2 to 5 are routine experimentation steps and are general state of art for a skilled artisan who would be motivated to use the same for reaching at the claimed composition in view of the cited TKDL documents. Therefore, claims 2 to 5 lack inventive step and does not constitute an invention u/s 2(1)(j) of the Patents Act, 1970.

**7.** In view of the above said, it is inferred that the amended claims 1 to 5 lack inventive step and therefore do not constitute an invention u/s 2(1) (j) of the Patents Act, 1970. Also the said claims fall u/s 3(p) of the Patents Act, 1970.

The application is refused for grant of patent

Date – 19/07/2013

(Dr NILANJANA MUKHERJEE)  
Assistant Controller of Patents and Designs