

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

In the matter of Patent Application No. 1642/DEL/2006
Filed on 17/07/2006
In the matter of hearing held u/s 14

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

Hearing u/s 14 held on 07/11/2012

Present --

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

Decision u/s 15

1. An application titled "A novel herbal composition effective against headache and a process for the preparation thereof" was filed by M/s L S Davar & Co., New Delhi on behalf of M/s Central Council for Research in Unani Medicine (CCRUM), New Delhi on 17/07/2006. The application claimed no priority.

2. The instant application was examined u/s 12 and 13 of the Patents Act, 1970 and the first examination report (FER) was issued on 04/03/2011. The applicant filed the reply to FER on 02/02/2012. The amended claims were examined and hearing notice was issued on 04/10/2012 with the following objections

2.1 Claims fall u/s 3(p) of the Patents Act, 1970 in view of documents cited from Traditional Knowledge Digital Library (TKDL);

2.2 Claims fall u/s 3(e) of the Patents Act, 1970;

2.3 Permission from National Biodiversity Authority (NBA) is required;

2.4 Source and geographical origin of the biological resource used in the application should be incorporated in the specification.

3. The agent amended the claims after hearing and the amended claims under consideration are as under

Claim 1 – A novel herbal composition effective against headache comprising 450-550 mg seeds of Tukhm-e-eSiras (*Albizia lebbek* (L.) Wild).

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

-extraction of siras seeds is carried out with water and alcohol in a ratio of 50:50-30:70, subjected to evaporation under reduced pressure of 280-320 mg of Hg,

-mixing of dry viscous mass thus obtained with preservative such as sodium benzoate having concentration of 0.1-0.15% and the diluents such as kaolin/ starch in an amount of 25-40%,

-drying the mixture at 80-105 degree c.

4. Regarding objection no. 2.1 and 2.2 –

4.1 The agent submitted that the method of preparing the composition is novel. The seed without treatment is not effective against headache. The 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.

5. Regarding objection no. 2.3 and 2.4 –

5.1 The agent submitted that the plants used are from Andhra Pradesh, India and NBA permission has been applied for.

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

6.1 The agents arguments that the cited TKDI references do not teach combination of standardized plant parts in certain ratio and process parameters is not persuasive.

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

("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.")

6.2 I observe that although the cited references do not specifically teach adding the ingredients in the amounts as claimed, however the references does teach the use of the plants, *Albezzia lebbeck*, in the treatment of headache. This reasonable expectation of success would motivate an artisan of ordinary skill to use the said plant parts for reaching at 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.

6.3 Further 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 parameters, the optimization of ingredient amount would have been obvious for a person having ordinary skill in the art.

6.4 I observe that the process steps as claimed in claim 2 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, claim 2 lack inventive step and does not constitute an invention u/s 2(1)(j) of the Patents Act, 1970.

6.5 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.

7. In view of the above said, it is inferred that the amended claims 1 and 2 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) and u/s 3(e) of the Patents Act, 1970.

The application is refused for grant of patent.

Date – 23/09/2013

(Dr NILANJANA MUKHERJEE)

Assistant Controller of Patents and Designs