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No. 1313/DEL/2006/....

Date - March 19, 2013

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

In the matter of Patent Application No. 1313/DEL/2006
Filed on 31/05/2006
In the matter of hearing held u/s 14

Central Council for Research of Ayurveda and Siddha (CCRAS), New Delhi.....The Applicant

Present

Smt Mona Saini of M/s L. S Davar & Co., New Delhi.....Agent of the Applicant
Dr Sulochana Bhatt, Dr Pramila Pant and
Mr Subhash Chandra Verma of CCRASRepresentative from the Applicant

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

Decision u/s 15

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

The claims relate to

A process for the preparation of a herbal preparation for the treatment of running and stuffy nose comprising in the step of:

- i)preparing coarse powder of cleaned kantakari (*Solanum xanthocarpum*) whole plant, Vasa (*Adhatoda vasica*) leaves, madhuyasti (*Glycorrhiza glabra*) root and Shati (*Hedychium spicatum*) rhizome separately and then mixed;
- ii)preparing Kwatha of the aforesaid plants by boiling with water in the ratio of 1:16 and reducing to one fourth;
- iii) filtering the kwatha;
- iv)adding sugar to kwatha and stirring till completely dissolved;
- v)adding honey after cooling to room temperature;
- vi)adding cardamom powder (*Elettaria cardamomum* seeds powder) -1 to 2% to step (v);
- vii)adding preservatives such as Sodium Methyl Paraben, Sodium Propyl Paraben and Sodium benzoate;

viii) storing and filtering through muslin cloth.

A herbal preparation for running and stuffy nose, comprising for every 10 ml of said preparation:

Kantakari- Solanum xanthocarpum (whole plant) -400 to 600 mg.

Vasa - Adhatoda Vasica (leaves) -400 to 600 mg.

Madhuyasti-Glycyrrhiza glabra (root) -400 to 600 mg.

Sh&ti-Hedychium spicatum (rhizome) -400 to 600 mg.

Sugar (I.P. Grade) -50 kg for 100 litre syrup

Madhu (Honey) -20 litre.

Elattaria cardamomum seeds -1 to 2%

2. The main technical objection raised vide letter dated 05/10/2012 were as follows

-that the claims lack novelty and inventive step in view of IN188649, CN1188650 and CN1054191 and Journal of Ethnopharmacology (Nov 1999), Vol 67, Issue 3, pages 361-365

-that the claims fall u/s 3(p) in view of the cited TKDL documents;

-that the claims fall u/s section 3(e) as the claimed composition does not show unexpectedly new property;

-prior approval from National Biodiversity Authority (NBA) is required; and

-further description of the source and geographical origin of the plant should be provided in the specification.

3. During hearing, the applicant argued that the amended claims 1 to 3 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 by using Ayurvedic Pharmacopoeial Committee (APC) guidelines, Department of Ayush;

-the plant parts have been combined in a certain ratio;

-process parameters are novel and the standard operating procedure (SOP) for the preparation of 100 litres for large scale production is scientifically developed;

-safety profile of the formulation has been established through preclinical safety/ toxicity studies;

-the present claims are different from the cited documents w.r.t its composition, combination, indication and drug development process.

The applicant submitted that the plants used are of Indian origin. The applicant submitted that they have applied for NBA permission.

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

4.1 Applicant's arguments have been carefully considered but are not deemed persuasive.

Applicant argues that the cited TKDL references do not teach combination of standardized plant parts in certain ratio and process parameters.

4.2 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."

4.3 I observe that although the cited references do not specifically teach adding the ingredients in the amounts claimed by the applicant, however the references does teach the use of the plants, kantakari (*Solanum xanthocarpum*), Vasa (*Adhatoda vasica*), madhuyasti (*Glycorrhiza glabra*) and Shati (*Hedychium spicatum*), in the treatment of respiratory disease. 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.

4.4 The applicant submitted that clinical trials of the claimed composition are going on. No data to show unexpected results or efficacy has been submitted by the applicant. Thus, in absence of some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amount is considered as a routine art and would have been obvious for a person having ordinary skill in the art.

4.5 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.

4.6 I observe that the process steps as claimed in claims 1 and 2 have been taken from standard operating procedure and 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 TKDI. documents. Therefore, the said claims lack inventive step and does not constitute an invention u/s 2(1)(j) of the Patents Act, 1970.

5. In view of the above said, it is inferred that the amended claims 1 to 8 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(e) and u/s 3(p) of the Patents Act, 1970.

The application is refused for grant of patent

(Dr NILANJANA MUKHERJEE)
Assistant Controller of Patents and Designs