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**No. 1576/DEL/2006/....**

**Date – December 27, 2012**

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

In the matter of Patent Application No. 1576/DEL/2006

Filed on 04/07/2006

In the matter of hearing held u/s 14

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

Present –

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

Dr Usama Akram, Research Officer, CCRUM.....Representative from the Applicant

**Hearing u/s 14 held on 11/12/2012**

**Decision u/s 15**

1. An application for grant of patent titled, 'A novel herbal composition effective against skin disorders and to a process for the preparation thereof' was filed by **M/s L S Davar and Co., New Delhi on behalf of** Central Council for Research in Unani Medicine (CCRUM), New Delhi on 04/07/2006. The application claimed no priority.

2. The application comprised 6 claims. Claims 1 to 3 were directed to a composition comprising (i) Maghz-e-Nimkoli (*Azadirachta indica*) 150-175 mg (ii) Rasaut (*Barberis asiatica*) 150-175 mg and (iii) Chaksu (*Cassia absus*) 150-175 mg. Claims 4 to 6 were directed to a process for the preparation of the composition comprising the steps of separately preparing an extract of Neem, Rasaut bark and Chaksu and mixing the three extracts.

3. The application was examined u/s 12 and 13 of the Patents Act, 1970 and first examination report (FER) was issued on 11/02/2011. The main technical objection raised were as follows

- that the claims do not constitute an invention u/s 2(1)(j) as the claims lack inventive step;
- that the claims fall u/s 3(p) in view of 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.

4. The applicant filed reply to FER on 20/01/2012. The claims were amended and reduced to two. Amended claim 1 directed to composition comprising (i) seeds of Maghz-e-Nimkoli (*Azadirachta indica*) 150-175 mg (ii) roots of Rasaut (*Barberis asiatica*) 150-175 mg and (iii) whole plant of Chaksu (*Cassia absus*) 150-175 mg.

Amended claim 2 directed to process for the preparation of the composition comprising the steps of separately preparing an extract of Neem, Rasaut bark and Chaksu; mixing the three extracts; kneading for half hour; kneaded mass dried at 85 deg c for 3 hours; and evaporating in hard gelatin capsule.

5. Second examination report along with hearing notice was issued to the applicant on 9/11/2012. The main technical objection raised in SER were as follows -

- that the claims do not constitute an invention u/s 2(1)(j) as the claims lack inventive step in view of cited TKDL documents;
- that the claims fall u/s 3(p) in view of 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.

6. Hearing u/s 14 was held on 11/12/2012.

7. During hearing, the applicant argued that the amended claims 1 and 2 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.



The applicant incorporated the source of plant (Hyderabad, Andhra Pradesh) in description. The applicant submitted that they have applied for NBA permission.

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

8.1 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.

8.2 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.")*

8.3 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 ingredients Maghz-e-Nimkoli, Rasaut and Chaksu as a composition to treat skin disorders. 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.

8.4 Further the clinical results furnished by the applicant shows 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 parameters, the optimization of ingredient amount would have been obvious for a person having ordinary skill in the art.

8.5 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.

8.6 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.

9. 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(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