

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

In the matter of patent application no. 1734/DEL/2007  
Filed on 14/08/2007  
In the matter of hearing u/s 14

M/s Central Council for Research in Unani Medicines, New Delhi.....The Applicant

**Hearing u/s 14 held on 27/02/2014**

Present

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

**Decision u/s 15**

1. An application titled as, "A novel herbal composition for the treatment of eczema and a process for preparation thereof" was filed by M/s L. S Davar & Co., New Delhi on behalf of M/s Central Council for Research in Unani Medicines, New Delhi 14/08/2007. The application claimed no priority.

2. The application was examined u/s 12 and 13 of the Patents Act, 1970 and the first examination report (FER) was issued on 07/09/2012. The applicant's agent filed reply to FER on 25/07/2013. Subsequent examination report with hearing notice was issued on 10/02/2014 having the objections as under

**2.1** The claims lack novelty and inventive step and do not constitute an invention u/s 2(1)(j) of the Patents Act, 1970 in view of the prior art documents as under

**D1** – US 6579543

**D2** – Formulation ID BP/1238; Formulation Name - Trijetyediyar am;

**D3** – Formulation ID RG/183; Formulation Name - Drekvedyame r am;

**D4** – Formulation ID AB/848; Formulation Name - Kandarpasgratailam.

Documents D2 to D4 have been retrieved from Traditional Knowledge Digital Library (TKDL).

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

**2.3** Claims fall u/s 3(p) of the Patents Act, 1970;

**2.4** Source and geographical origin of the biological material used should be given in the specification. If the said biological material has been obtained from India, then approval from National Biodiversity Authority (NBA) is required to be submitted to this office.

3. The claims under consideration are as under

**Claim 1** –

1. A novel herbal composition for the treatment of eczema comprising of:

Post-e-Neem (Bark of <i>Azadirachta indica</i> )	12-20%
Kafoor (Camphor)	1-4%
Sesame Oil ( <i>Sesamum indicum</i> )	75-85%

2. A process for preparation of a novel herbal composition for the treatment of eczema comprising steps of:

extraction of Post-e-neem to obtain extract with petroleum ether which is mixed in sesame oil with stirring followed by addition of Kafoor and filtration to obtain the composition.

**Claim 3** is dependent on claim 2.

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

**Regarding objection u/s 2(1)(j)**

4.1 It is observed that none of the prior art discloses all components of the instant claimed composition being used together in a single composition with specific weight ratios. Therefore, the cited documents cannot be considered as novelty destroying for the instant claims.

4.2 It is observed that the constituents of the instant claimed composition are known for their effect on eczema and other dermatoses through the cited documents.

D4 teaches all the three ingredients viz. Neem, Camphor and Sesame, for making therapeutic formulation for treatment of eczema.

D2 teaches therapeutic composition comprising Neem and Camphor for treatment of eczema.

D3 teaches therapeutic composition comprising Neem and Camphor for treatment of leprosy and other dermatoses.

D1 teaches composition comprising Neem, Camphor and Sesame, for treatment of variety of skin ailments. D1 teaches that Neem has anti-inflammatory effects to provide relief from at least one of swelling, redness, fever and inflammation (col.2 lines 54-57 and col.3 line 6); Camphor possess soothing analgesic effects (col. 2 lines 40, 41 and 49); and Sesame oil acts as transdermal carrier that penetrate the skin and quickly aid in transport of other components. (col. 17 lines 40-45 and 61).

4.3 Generally, it is prima facie obvious to select a known material for incorporation into a composition based on its recognized suitability for its intended use. All the cited references teach that Neem, Camphor and Sesame are useful in treatment of skin related disorders, in particular eczema as taught by D2 and D4. D1 teaches the way of working of Neem, Camphor and Sesame.

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.")*

I also rely on Terrell on Law of Patents (para 12-17) in this regard

*'.....If information is part of the common general knowledge then it forms part of the stock of knowledge which will inform and guide the skilled person's approach to the problem from the outset.'*

Therefore, a skilled artisan familiar with the cited references and interested in improving the efficacy of the compositions/ formulations taught in the cited documents, would have sufficient guidance to add, without the exercise of inventive skills, the three ingredients (neem, camphor and sesame) as claimed, together in a single composition useful in treatment of eczema.

4.4 It is observed that the said prior art documents do not teach the specific amounts of the components and the process parameters as claimed in the instant application. However, it would be obvious to a person having ordinary skill in the art to modify conventional working conditions such as amounts, temperature, pressure etc needed because it is deemed to be merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

In this context, 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.")*

4.5 It is observed that the instant specification does not disclose any example or data to show any surprising or unexpected results of the composition as claimed. Also there are no example or data to show that the particular amounts of components in combination as claimed delivers enhanced results than if used in other amounts.

In absence of some demonstration of unexpected results from the claimed parameters, this optimization of working conditions is considered obvious.

4.6 It is observed that the process steps as claimed 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 documents. Also the instant specification is silent as to how the said conventional process steps are resulting into any effective composition.

In this context, I quote the observation made by Arnold J, the Court of Appeal ([2010] EWCA Civ 1260)

*"...even if information is neither disclosed by a specific item of prior art nor common general knowledge, it may nevertheless be taken into account as part of a case of obviousness if it is proved that the skilled person faced with the problem to which the patent is addressed would acquire that information as a matter of routine. For example, if the problem is how to formulate a particular pharmaceutical substance for administration to patients, then it may be shown that the skilled formulator would as a matter of routine*



*start by ascertaining certain physical and chemical properties of that substance (e.g. its aqueous solubility) from the literature or by routine testing. If so, it is legitimate to take that information into account when assessing the obviousness of a particular formulation. But that is because it is obvious for the skilled person to obtain the information, not because it is common general knowledge."*

4.7 The dependent claim 3 does not contain any features which, in combination with the features of any claim to which they refer, meet the requirements in respect of inventive step.

In light of the above discussion, the claims 1 to 3 lack inventive step and do not constitute an invention u/s 2(1)(j) of the Patents Act, 1970.

#### **Regarding objection u/s 3**

4.8 It is observed that the instant specification is silent regarding enhanced efficacy or unexpected surprising results. No comparative analysis or data has been submitted by the applicant regarding the same or to show any synergistic effect of the ingredients (neem, camphor and sesame) when combined in the particular amounts as claimed to deliver enhanced results than if used in other amounts. In absence of some demonstration of unexpected results from the claimed composition and the specified amounts, the claims 1 to 3 fall u/s 3(c) of the Patents Act, 1970.

4.9 The anti-eczema therapeutic potential of combination of neem, camphor and sesame is disclosed in prior art documents D2 to D4. 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 1 to 3 fall u/s 3(p) of the Patents Act, 1970.

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

#### **The application is refused for grant of patent**

**Date – 10/03/2014**

**(Dr NILANJANA MUKHERJEE)**  
Assistant Controller of Patents and Designs