

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

In the matter of patent application no. 1735 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 DelhiAgent of the applicant

Dr AkramRepresentative of the applicant

Decision u/s 15

1. An application titled as, "A novel herbal composition for the treatment of sinusitis 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 23/01/2013. The applicant's agent filed reply to FER on 27/12/2013. Subsequent examination report with hearing notice was issued on 03/02-2014 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 – Formulation ID – BP/1007; Formulation Name – Jet-phaledyava[®]ike;

D2 – Formulation ID – AT-149; Formulation Name – A[®]agunama[®]a[®];

D3 – Formulation ID – NA4/553; Formulation Name – Joshanda Barae Zeequnnafs;

D4 – Formulation ID – NA4/4316; Formulation Name – Laooq Zufa;

D5 – Formulation ID – HG/492; Formulation Name – lavajri[®]va[®]ike;

D6 – Formulation ID – HG/500; Formulation Name – gerebhran;

D7- <http://www.jerows.com-handbook.html>, Handbook of Traditional Tibetan Drugs -Their Nomenclature, Composition, Use, and Dosage : T.J.Tsarong; AUG-CHOS 7 - INCARVILLEA 7.

Documents D1 to D6 have been retrieved from Traditional Knowledge Digital Library (TKDL).

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

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

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

2.5 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 preparation for the treatment of sinusitis comprising of Iris Ensata Thumb and Piper Nigrum Linn.
2. A process for preparation of a novel herbal preparation for the treatment of sinusitis comprising steps of: grinding of Iris Ensata Thumb and Piper Nigrum Linn followed by extraction of filtered Iris Ensata Thumb and piper Nigrum Linn and drying.

Claims 3 to 6 are 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 sinusitis through the cited documents.

D1 and D2 teach the use of Piper nigrum for the treatment of all types of diseases with Vata predominance, cough, bronchitis etc.

D5 teach the use of Piper nigrum for treatment of all types of diseases with kapha and vata predominance; cough, bronchitis etc.

D6 teaches the use of Piper nigrum for the treatment of Sinusitis and all types of diseases with kapha and vata predominance.

D3 and D4 teach the use of Iris ensata Thumb for treatment of bronchial asthma and chronic cough.

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. It is known in the art that sinusitis, cough, bronchitis etc are different types of respiratory tract infections, which are also named as 'kapha dosha' in Ayurveda. Therefore, the cited references D1 to D6 teach that Piper nigrum and Iris ensata Thumb are useful in treatment of kapha and vata predominance; cough, bronchitis etc., in particular sinusitis as taught by D6.

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 ingredients (Piper nigrum and Iris ensata Thumb) as claimed, together in a single composition for use in the treatment of sinusitis.

4.4 It is observed that the said prior art documents do not teach the specific ratio's of the composition and 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 is no example or data to show that the particular ratio of components in combination as claimed delivers enhanced results than if used in other ratio's.

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 agent submitted that the cited references do not teach the use of Kaolin in the preparation of the composition. It is observed that Kaolin is traditionally known in the art as diluent in tablet preparation (Natural Medicines Comprehensive Database; <http://naturaldatabase.therapeuticresearch.com/nd/PrintVersion.aspx?id=44&AspxAutoDetectCookieSupport=1>). Therefore, the dependent claim 3 to 6 do 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 6 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 (Piper nigrum and Iris ensata Thumb) when combined together in the particular ratio as claimed to deliver enhanced results than if used in other ratio's. In absence of some demonstration of unexpected results from the claimed composition, the claims 1 to 6 fall u/s 3(d) and 3(e) of the Patents Act, 1970.

4.9 The anti-sinusitis therapeutic potential of combination of Piper nigrum and Iris ensata Thumb is disclosed in prior art documents D1 to D6. 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 6 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 6 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(d), 3(e) and 3(p) of the Patents Act, 1970.

The application is refused for grant of patent

Date – 10/03/2014

(Dr NILANJANA MUKHERJEE)
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