

## **Patent Office Issues Guidelines for Processing of Applications Relating to Traditional Knowledge and Biological Material**

Following DIPP's notification regarding revocation of Avesthagen Ltd.'s patent titled "A Synergistic, Ayurvedic/functional food bioactive composition (Cinata) and a process of preparation thereof" the Patent Office has issued guidelines to be complied by all Examiners and Controllers while processing patent applications relating to Traditional Knowledge and/or biological materials.

The salient features of the guidelines are as follows:

### **SCREENING**

- The Receipt, EDP, Classification and Screening Section (RECS) is directed to correctly identify screen and classify applications relating to TK as "**Traditional Knowledge**". The System Administrator is further directed to create separate screening fields namely **TK-Chemical, TK-Biotechnology** and **TK-Mechanical** in the Module.

### **ALLOTMENT**

- In the Concerned Group, the Group Leader shall act as Controller for all applications related to TK and shall select one suitable Examiner from within the group to deal with such applications. The Group Leader is further directed to upgrade their knowledge about TK and Biological Resources.
- Any application or case relating to TK including the pre grant opposition that are already under process are directed to be re-allotted to the identified pair in the respective Group.

### **EXAMINATION**

- The Examiners are directed to send a copy of citation (English translated) along with the Examination report, if any such citation is found from the TKDL database.

- Guiding Principle for assessment of Novelty- Subject matter relating to extracts/alkaloids and/or isolation of active ingredients of plants, which are naturally or inherently present in plants not to be considered as novel when use of such plants is pre known as part of teachings of Traditional Knowledge.
- Guiding Principle for assessment of Inventive Step- Combination of plants with known-therapeutic effect with further plants with the same known therapeutic agents wherein all plants are previously known for treating the same disease to be considered as obvious combination.
  - In case an ingredient is already known for the treatment of disease, then it creates presumption of obviousness that a combination product comprising the known active ingredient would be effective for treatment of same disease.
  - Discovery of optimum or workable ranges of traditionally known ingredients by routine experimentation would not be considered to be inventive
  - Taking out one single component out of multiple ingredients known to have same therapeutic activity as per traditional knowledge would not be considered as inventive
  - In case where individual ingredients are known for treatment of a disease as a part of Traditional Knowledge then it would be obvious that a combination product comprising such ingredients with further plants having the same known therapeutic effect would be more effective than each of the medicinal plants applied separately.

*The notification explains the aforesaid guidelines by way of several illustrations and analysis.*

- Section 3 (c), (e), (i), (j), and (p) of the Patents Act are to be strictly followed, when deciding the patentability of subject matter relating to TK or biological matter
- The patent would not be granted unless the permission from the National Biodiversity Authority is submitted by the applicant in case where invention uses the biological material from India or the source and/or the origin of the biological material is from India as per the disclosure in the specification.

- The source and geographical origin of the biological material is to be clearly is to be clearly specified in the specification by incorporating a separate heading/paragraph in the beginning of the description.

Publication of list of TK related patent applications:

- The System Administrator is directed to publish the list of all pending patent applications related to TK in a separate link on the CGPTDM's website. The list would be automatically updated as per the screening field in the module on real time basis.
- A list of all patents granted on applications related to TK from July 1, 2012 onwards is also to be displayed on website.

The office of the Controller General of Patents, Designs and Trademarks have also invited comments/suggestions on the aforesaid guidelines which can be sent via e-mail to [a.chakaraborti@nic.in](mailto:a.chakaraborti@nic.in) latest by November 22, 2012.

The notification can be accessed from the following link:

[http://www.ipindia.nic.in/iponew/TK\\_Guidelines\\_08November2012.pdf](http://www.ipindia.nic.in/iponew/TK_Guidelines_08November2012.pdf)