

Brainstorming Session

Patenting of Traditional Knowledge/herbals In India

A session to discuss the issues

Organized by

M/S Gopakumar Nair Associates and Pravin Gandhi
College of Law

Venue : Moot Court Room, Pravin Gandhi College of Law, Mithibai
College Building, Vile Parle (West), Mumbai - 400 056

15th February, 2013.

BACKGROUND

Herbal products like all other products can also be protected from copying and get various forms of rights from the government. Since the rights are granted by the state for a property that has emanated from the use of mind or intellect these are called as intellectual property rights. Four different types of IPR's are possible namely patents, trademarks, designs and copy rights.

Patents are exclusive protection granted by the state to inventors who disclose the invention to the state. The Indian patent act as undergone major changes and now offers provisions for protection of processes, products and a combination of process cum product. Patents are granted for inventions and not for discoveries. Patents are not granted if the invention is no- obvious.

Patents are granted for

Inventions and not for discoveries

Rights given to Inventor by the State on disclosure of Invention

Rights are for specified territory and for specified period

Criteria for granting Patents are

Prior art [documented, published, in public domain]

Inventive step

Useful to Society (Animals and Man)

Obviousness

Patents can be for

Process

Product/Composition

Process cum Product

- Inventive step is important especially in case of herbals as, a large pool of data is in public domain through Traditional knowledge and documented books. In fact the Traditional Knowledge Digital Library (TKDL) created by the Government has actually reduced the possibility of obtaining patents for herbals known in TK (Ayurveda).
- Hence there are Challenges in overcoming Absolute Non-Patentability in Herbal Drugs. These are due to the following clauses in the Indian Patent act.
-
- Section 2 (1) (j) : “invention” means a new product or process involving and inventive step and capable of industrial application.
- Section 2 (1) (ja): "inventive step" means a feature of invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person
 - Skilled in the art.
- Section 3 (c) : the mere discovery of a scientific principle or the formulation of 20 [or discovery of any living thing or non-living substance occurring in nature];

- However this does not mean that it is impossible to get patents for herbals.
- It is important to know the basics of what can be and what cannot be patented when it fall in Herbals area, which are highlighted in brief below;
-
- Patents are NOT granted for-
 - Non-obvious inventions
 - Those known already –documented, Traditional knowledge [Oral TK??]
 - Those occurring in nature e.g. piperine, taxol, baccosides, cultivars, etc
 - New use of a known substance.
 - frivolous inventions

- Patents are/SHOULD BE grantable for- (UPON MEETING THE INVENTIVE STEP CRITERIA)
 - Processes that show improvements than known already e.g. Better extraction processes, better dosage forms, stable formulations, better tastes/aroma,
 - Processes that can give plants that give higher yields[not just hybrids]
 - Processes that involve biotechnological interventions,
 - Processes that improve bioavailability,
 - Processes that provide synergy/antagonistic activity
 - Processes for Standardization, fractionation, isolation, etc.

- Patents are grantable for- [products](UPON MEETING THE INVENTIVE STEP CRITERIA)
 - Formulations that are unique,
 - Unique combinations involving selection of – specific items/ingredients; specific proportions; specifically processed mats;
 - Unique combinations that show synergy/antagonisms- resulting in better activity OR lesser AE's; better stability, better absorption/BA;
 - Unique combinations with Formulation aids that show inventive steps-can be even addition of -perfume/flavor or stabilizers or penetration enhancers Or change formats that provide benefit to users etc.
 - Uniquely standardized to provide specific quality those are responsible for activity e.g. Ratios of components etc.
 - Uniquely delivered for e.g. Taxol injections-3 hr/12 hr/8 hr through special tubing's.



IPR&HERBALS



**DRFAT
IDELINES.PATENTSO**

