HERBAL DRUG PATENTING

DR. D. N. RAUT

Intellectual Property Rights

- It defined as the Legitimate rights of the inventor for protection of his intellectual property thus excluding others from making, copying, using or selling his proprietary subject matter

- An investor , having spent huge money and efforts, requires a sort of protection for his intellectual property. Such protection allows him to gain the deserved incentive for his innovation/invention. IPR provides such protection.

“Necessity is the Mother of Inventions” (in Ancient Times)

- **Necessity in Modern Times/ Compulsions to Invent and Patent**.
  - Creating absolute monopolies in method of treatment and medicines
  - Increase market share
  - Putting competitors out of business
  - Higher Salary, perks and royalty for Scientists
  - Litigation Opportunities for Lawyers

- Indian Bayh Dole Act
  (Public Funded IP Bill) 2008

WHAT IS PATENT?

- It is a grant by a state to an inventor or to his assignee , giving exclusive rights to make, use, exercise and vend the inventions for a limited period, in exchange for disclosure in a patent specification. (contract b/n a nation and inventor)

- Patentee - A claimer of the patent

THE PATENT ACT 1970

According to the act:

1. A new invention

2. It should be new and non- obvious with respect to prior art

3. It must useful

4. Not previously in use in India Invention , as per the act may be defined as any new and useful

PATENTABLE (From pharmacy)

1. New process of manufacture
2. NCE (New chemical entities, after 2005)
3. New formulation processes
4. New composition of matter

New use of known herbs/extracts

- Patentable in India – only through novel dosage forms/formulations OR synergestic combinations [3(c)]
- Patentable in Europe – Even through known dosage forms, if efficacy in new indication is demonstrated.
- Patentable in USA – preferably as a Method of Treatment

Method of Treatment – Not Patentable in India [(Sec. 3(i)]

NON-PATENTABLE (In INDIA)

1. Discoveries
2. Methods of detection, diagnosis or treatment of diseases
3. Analytical methods
4. Methods of agriculture/cultivation
5. The products made by Chemical synthesis
6. Animal, plant, and biological methods for growing and rearing them

PATENTABLE NATURAL PRODUCTS

I. Formulation of new composition or improved formulation is patented

Eg: Patented herbal antiallergic composition which comprises a synergistic mixture of extracts from the fruits of *Terminalia chebula*, bark of *Albizia lebbeck*, *Terminalia bellerica* and *Embblica officinalis* and process of preparation of such composition.

The invention also contains the fruits of *Piper longum*, *Piper nigraum* and rhizomes of *Zinger officinalae* and thoroughly mixed to get the final composition which has potent antiallergic activity.

The preparation is useful for the treatment of allergic conditions.

II. Patent for new use of the herbal constituents

Eg: The weight loss properties of Forskohlin (obtained from the roots of *Coleus forskohlli*) were discovered by the firm (Sabinsa corporation), in humans, which is not a traditional use of the Coleus active.

For this, the company was granted a patent for its use and composition in promotion of lean body mass, reduction of adipose tissue (fat) and weight loss.

III. Modification or Synthesis of the natural compounds

Eg: The novel steroidal glycosides compounds which are extracted and isolated from the extracts of plant of the genus Trichocaulon or Hoodia containing an appetite suppressant agent and the derivatives of such compounds are synthesized with the aim of increasing the activity of the active ingredient.

Also, this invention provides novel intermediates for the synthesis of active compound .

The active ingredient in the *Hoodia gordonil* plant is called P57 and is responsible for its appetite suppressant qualities. Phytopharm, a British pharmaceutical company, has the exclusive patent on P57

IV. A Novel isolation process

Eg; For the process of isolation of Azadirachtin (fungicidal activity) from the seeds of neem and also its storage. N.C.L, Pune, Indian patent

V. A new application of an isolated compound

Eg; For the use of turmeric as a stabilising agent for menadione, an antifungal agent- Japanes patent.

VI. The inventions with novelties

Eg; Bio-pesticides

VII. Biotechnology related products

VIII. Purification of the natural products

Challenges in overcoming Absolute Non-Patentability in Herbal Drugs

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.

Herbal Powders/Pastes/juices – in Capsules , Liquids or other dosage forms (Naturally Occurring)

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]

Impact of – Prior Art
– Traditional Knowledge
– Known uses
– Known dosage forms

Overcoming Prior Art

- New Techniques/processes
- Novel dosage forms of known herbs
- New uses (?) - approaches

Challenges in India

- Severe resistance from powerful lobby of Ayurvedic industry and profession
- Poor status of standardization and characterization
- Lack of clear Regulatory/Clinical guidelines and roadmap.
- Absence of National/Governmental awareness on high global potential.
- Indian mind-set issues.

Non-obviousness / Inventive Step

Will need to "invent" product/process not obvious to a person skilled in the art.

Ex: - Acquous Extract of Herb, – known Alcoholic/Solvent extract of Herb

Additional Step – Characterization, – Standardization, – Marker Compound Isolation, – Marker Compound Identification, – Fingerprint approach

Use of chromatography techniques

Comparative study over powder or known extract

Enriched fractions

Newer extraction techniques

Pre-treatment/multi treatment

Patentability Filter

- Prior use/ prior publication/ prior disclosure
- Industrial applicability
- Novelty
- Non-obviousness- inventiveness
- Sec.3- Not patentable
- Written description / enablement requirements
- Application/ specification/ claims
- Patent prosecution
- Maintenance / Defense after grant

Well Known Proven Herbs with Extended Research

- **Circumin and Circuminoids** Potential Few selected examples- 1612/CHE/2005 titled 'A Combination Antimalarial Drug Therapy With Curcumin And Artemisnin'
- **Piperin-** 1476/MAS/1995 titled 'Use Of Piperine As A Bioavailability Enhancer'
- **Picroliv (Kutkin)** - 661/CAL/1999 (WO/2001/007062) titled A Synergistic Composition (Glycyrrhizia Glabra and Picrorhiza kurroa) for the treatment of liver and liver associated ailments and a process for preparing the same
- **Gingerin-** US 2008300304 titled 'Ginger Fraction For Inhibiting Human Cyp Enzymes '

Patent Literature Analysis on Herbal Medicine

- 70% - 75% China
- 10% - 15% Japan
- 5% - 10% Korea
- 2% - 5% India
- Rest Africa and Latin America

Most herbal patents found in US and China (US and CN direct or through PCT)

Patenting Opportunities in India

- Heavily Restricted with controls and interference
- Limited Patenting Opportunities
- Impractical Biodiversity Act.
- Declaration of source and origin
- Absence of clear regulatory guidelines in herbal research.
- Apathy at all levels

Patenting Opportunities in USA and Developed Countries

- High Appreciation and acceptance for Natural and Herbal based Medicines.
- Prioritized introduction of regulatory System
- Open mindset and acceptance of traditional medicine.
- Keenness to adopt assimilate and absorb herbal/traditional knowledge based technologies.

Opportunities

- Indian Scientists and Research Labs should work closely, intensively and passionately to develop herbal products for advanced medical treatment in collaboration with US, European research labs/univ.
- Patent the findings-product, process etc. globally/through PCT route.
- Support strong model of sustainable development of herbal resources without endangering the species in developing and under-developing countries.
- Have open mindset for practicable benefit sharing business model.

The Patents Act, 1970

- Sec.3(p) - Inventions not Patentable
  - *"an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties or traditionally known component or components"*
- Sec.10(4)(D) - Contents of Specification
  - *"disclose the source and geographical origin of the biological material in the specification, when used in an invention".*
- Sec.25(1)(k) - Pre-grant Opposition & Sec.25(2)(k) - Post-grant Opposition
  - *"That the invention so far as claimed in any claim of the complete specification is anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere"*
- Sec 64(q) - Revocation proceedings
  - *"That the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere"*

The Biological Diversity Act, 2002

- Sec.6

  (1) ***No person shall apply for any intellectual property right, by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application:***

  Provided that if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned:

  Provided further that the National Biodiversity shall dispose of the application for permission made to it within a period of ninety days from the date of receipt thereof.

  (2) ***The National Biodiversity Authority may, while granting the approval under this section, impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights.***

  (3) The provisions of this section shall not apply to any person making an application for any right under any law relating to protection of plant varieties enacted by Parliament.

  (4) Where any right is granted under law referred to in sub-section (3), the concerned authority granting such right shall endorse a copy of such document granting the right to the National Biodiversity Authority.

Biodiversity Appln. Form

FORM III
(See rule 18)

Application for seeking prior approval of National Biodiversity Authority for applying for Intellectual Property Right

1. Full particulars of the applicant

- Name
- Address:
- Professional profile
- Organizational affiliation (Please attach relevant documents of authentication):

2. Details of the invention on which IPRs sought

3. Details of the Biological resources and /or associated knowledge used in the invention.

4. Geo-graphical location from where the biological resources used in the invention are collected

5. Details of any traditional knowledge used in the in the invention and any identified individual /communiti\y holding the traditional knowledge

6. Details of institution where Research and Development activities carried out.

7. Details of economic, biotechnological, scientific or any other benefits that are intended, or may accrue to the applicant due commercialization of the invention.

Declaration

I/we declare the Information provided in the application form is true and correct and I /We shall be responsible for any incorrect / wrong information.

Signed
Name
Title

Place
Date

Letter from Biodiversity Authority

NATIONAL BIODIVERSITY AUTHORITY

Dr. K. VENKATARAMAN
Secretary
Telefax: 044 - 24491390
Mobile: (0) 94440 18146
E-mail: nba_india@vsnl.net

475, 9th South Cross Street,
Kapaleeswarar Nagar,
Neelankarai,
Chennai - 600 041.
Tamil Nadu. India

NBA/TECH APPL/9/183/08/08-09/

20-11-08

To
Dr.Dhurjati Sarvamangal,
Plot No.308, Visalakshi Nagar,
Vishakhapatanam -43,
Andhra Pradesh.

Sir,

Sub: Final Approval for seeking IPR (Form III) application under section 6 of the Biodiversity Act 2002 and Rule 18 of the Biodiversity Rules 2004- reg.

Ref: Your application letter dt. 11-04-2008.

With reference to your application in Form III for approval, I am to inform you that the application made by you in Form III for seeking IPR on the Method for the production of ethanol from *Muntingiya calabura* mentioned therein has been finally approved by the National Biodiversity Authority under section 6 of the Biodiversity Act 2002 and Rule 18 of the Biodiversity Rules 2004.I am herewith enclosing a copy of the mutually/duly signed stamp paper Agreement(ie. Agreement signed NBA and the Applicant) for your reference.

Thanking you,

Yours sincerely,

(Dr. K. VENKATARAMAN)

Encl.: One copy of the mutually signed stamp paper Agreement.

Approval (NOC) from Biodiversity Authority

NATIONAL BIODIVERSITY AUTHORITY

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NBA/TECH APPL/9/108/06/07-08/ 3293 05.11.2007

To
Shri. Govind Maruti Wagle,
T123, Marie Mandir,
Per Seravali,
Salcette,
Goa – 403 708.

Sir,

Sub: Final Approval for Form III (IPR) - Herbal Seed extract in the form of Pharmaceutical composition comprising the kernel *Apocynaceae thevetia peruviana, Thevetia nerifolia, Cascabela thevetia* and *Cascabela nerifolia* – Returning of mutually signed Stamp paper Agreement copy&Final approval for your application in Form III-Reg.

Ref:1. Your application dt. 18-12- 2006.
2. NBA letter dt.22-03-2007
3. Your letter dt 08.10.2007.

With reference to your application in Form III (IPR) for approval, I am to inform you that the application made by you in Form III (IPR)forInvention of Herbal Seed extract in the form of Pharmaceutical composition comprising the kernel *Apocynaceae thevetia peruviana, Thevetia nerifolia, Cascabela thevetia* and *Cascabela nerifolia* has been approved by the National Biodiversity Authority as per Section 6 of the Biological Diversity Act, 2002 and Rule 18 of the Biological Diversity Rules, 2004. I am herewith enclosing a copy of the mutually / duly signed Stamp Paper Agreement (ie. Agreement signed by the NBA and Applicant) for your reference.

Thanking you.

Yours sincerely,

(Dr. K. VENKATARAMAN)

BIOPIRACY

- Biopiracy describes a process in which living resources or traditional knowledge and practices are patented, thus applying intellectual property restrictions to their use

- Biopiracy refers to the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions that seek exclusive monopoly control (patents or intellectual property) over these resources and knowledge.
- It believes that intellectual property is predatory on the rights and knowledge of farming communities and indigenous peoples.
- Through nanotechnology- and synthetic biology-related patents, intellectual property claims are now being extended to elements of the periodic table and to key metabolic pathways involved in cellular functioning (and resulting in natural products with high commercial value).

Biopiracy: when indigenous knowledge is patented for profit

- Often, in the search for new bioresources, researchers draw on local people's traditional knowledge about the properties of a particular plant, animal or chemical compound.
- When researchers use traditional knowledge without permission, or exploits the cultures they're drawing from – it's called biopiracy.

- Biopiracy happens when researchers or research organisations take biological resources without official sanction, largely from less affluent countries or marginalised people.
- Biopiracy is not limited to drug development. It also occurs in agricultural and industrial contexts. Indian products such as the neem tree, tamarind, turmeric, and Darjeeling tea have all been patented by foreign firms for different lucrative purposes.

- Since 1994, the Agreement on Trade-Related Aspects of Intellectual Property Rights has required WTO member countries to develop legal frameworks to protect varieties of plant and animal resources in two systems: one for agricultural contexts and the other for pharmaceutical, chemical, textile, or other commodity contexts. Several countries have considered this to be counterproductive for protecting their bioresources.
- Since the early 2000s, many national governments have changed their laws to protect their bioresources, in accordance with the 1992 Convention on Biological Diversity.