



सत्यमेव जयते

WIPO Seminar on Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions: Regional and International Dimensions

June 23 to 25, 2015

Roundtable 4: Collections, Registers and Databases relating to Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions: Issues and Practical Experiences

Dr D Usha Rao
Assistant Controller of Patents and
Designs
Intellectual Property Office

INDIA



Traditional Knowledge/ Genetic Resources in India

India is one of the identified mega diverse countries rich in biodiversity.

With only 2.4 per cent of the earth's land area, India accounts for 7-8 per cent of the recorded species of the world

India is rich in associated traditional knowledge, which is coded as in ancient texts of Indian systems of medicines such as Ayurveda, Unani and Sidha,

A lot of Non-coded material also exists in oral undocumented traditions.

What is Traditional Medicine ?



“Traditional Medicine includes diverse health practices, approaches, knowledge and beliefs incorporating plant, animal and/or mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent illness.”

Use of Traditional Medicines



| | | |
|--|--|--|
| Populations using traditional medicine for primary health care | Ethiopia India Rwanda Tanzania Uganda | 90% 70% 70% 60% 60% |
| Populations in developed countries who have used complementary and alternative medicine at least once | Canada Australia France USA Belgium | 70% 48% 49% 42% 31% |

Courtesy CSIR

Status of Indian System of Medicines

| System of Medicine* | Registered practioners | Hospitals | Dispensaries | Colleges | Graduates Annual | Post-Graduates Annual |
|---------------------|------------------------|-------------|--------------|------------|------------------|-----------------------|
| Ayurveda | 3,66,812 | 2189 | 14252 | 154 | 6300 | 437 |
| Unani | 40748 | 189 | 966 | 31 | 1252 | 55 |
| Siddha | 12911 | 204 | 357 | 2 | 150 | 24 |
| Naturopathy | 402 | 21 | 55 | - | - | - |
| Total | 420873 | 2603 | 15630 | 187 | 7702 | 516 |

*more than 1000 years old

Courtesy CSIR

Extent of Misappropriation

(Ayurveda, Unani & Siddha)

Study Carried Out in March 2000

4896 references on 90 medicinal plants in USPTO patent databases

80% of references on seven medicinal plants of Indian Origin.

Kumari, Mustaka, Tamraparna,
Garjara, Atasi, Jambira, Kharbuza

Almost 50% of patents linked to traditional medicine

STUDIES ON PATENTS ON MEDICINAL PLANTS

| | | |
|---|---|-------|
| ■ March 2000 | : | 4896 |
| ■ March 2003 | : | 15000 |
| ■ December 2005 | : | 35587 |
| ■ December 2008 | : | 85000 |
| ■ Medicinal Plant Patents / Year | : | 5000 |
| ■ Possible Patents concerning Indian Plants / Year | : | 4000 |
| ■ Possible Patents on Indian system of Medicine on yearly basis | : | 2000 |
| ■ Annual average Growth Rate between 2000-2008 | : | 200% |

Courtesy CSIR

Protecting TK and GR in India Multi- pronged strategies



Accession to Treaties

- **Accession to Convention on Biological Diversity (CBD):** The Convention has three main goals:
 - ❖ conservation of biological diversity (or biodiversity);
 - ❖ sustainable use of its components; and
 - ❖ fair and equitable sharing of benefits arising from genetic resources
- **Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (India Accession 17th September 2001)**
- **Discussions under IGC**

National legislations

Biological Diversity Act 2002



Protection of Plant Varieties and Farmers' Rights Act



The Patents Act 1970



Biological Diversity Act 2002



- For preservation, conservation and use of biological resources and associated knowledge occurring in India for commercial or research purposes or for the purposes of bio-survey and bio-utilisation.
- National Biodiversity Authority
 - for **prior informed consent** for access and use of traditional knowledge and biological resources
 - making **application for intellectual property rights** (IPRs) relating to Indian biological resources with prior permission and
 - **for equitable sharing of benefits**
- State Biodiversity Boards (SBB) in 28 States along with 31,574 Biological management committees across India.
- **INDIAN REPOSITORIES** for Flora, Fauna, Microorganisms, Viruses, Insects
- National Biodiversity Fund for
 - benefits to the benefit claimers;
 - conservation and promotion of biological resources and
 - development of areas from where such biological resources or
 - knowledge associated thereto has been accessed;
 - socio-economic development of areas

Protection of Plant Varieties and Farmers' Rights Act



- Protection to the breeders for new varieties of plants and seeds
- Protection of farmer's rights to save, use, exchange and sell farm-saved seed
- Provisions for determination for benefits sharing
- Establishment of National Gene Bank to deposit seeds or propagating material including parental line seeds of registered variety

The Patents Act 1970



- Exclusion of inventions from patenting under section-3
- (e)- "a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or process for producing such substances
- (p)-"an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components"
- Sufficiency of disclosure under section 10(4)
 - Deposition of the material to an International Depository Authority (IDA) under the Budapest Treaty if such material is not available to public
 - disclosure of the source and geographical origin of a biological material used in an application for a patent
- Non- disclosure or wrong mention of the source or geographical origin of biological material used for an invention in the complete specification is a ground for **pre- and post- grant opposition under section 25** and also for **revocation** under section 64

Traditional Knowledge Digital Library

Know the Knowledge



Protect (Defensive)

Deal with possible misappropriation

Rights on knowledge get recognised in the Patent System

Traditional Knowledge gets misappropriated in the International Patent System due to lack of access to such knowledge Systems by the Patent Examiners

Current status of transcription of the traditional
medicine formulation in the Traditional knowledge
Digital Library

| Discipline | No. of texts (including volumes) used for transcription | Transcribed |
|-------------------|--|--------------------|
| Ayurveda | 75 books | 97,337 |
| Unani | 10 books | 1,75,150 |
| Siddha | 50 books | 23,016 |
| Yoga | 15 books | 1,680 |
| Total | 150 books | 2,92,662 |

OBJECTIVES OF TKDL

**Preventing
Misappropriation of
Indian Traditional
Knowledge**

**Break Format &
Language barriers**

**Multilingual (French,
German, Japanese,
English & Spanish)**

**Current use by Patent
Offices**

**Deliberations on IPC-
TKRC concordance list of
the new main group
A61K 36/00**

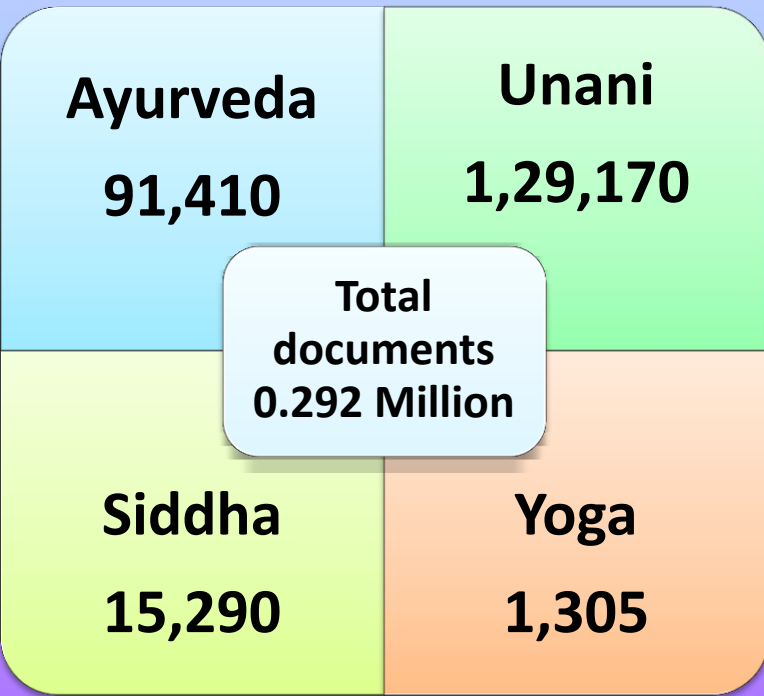
**Request to make TKDL
part of Minimum
Documentation under
PCT in 2015**

TKDL

**safeguards 0.250 million
medicinal formulations
like Neem and Turmeric
in Ayurveda , Unani and
Siddha**

**present in 34 million A4
size pages, at
International Level**

Traditional Knowledge Digital Library



TKDL Access Agreement with ISAs

| | |
|------------|--------------------------------|
| Feb 2009 | • European Patent Office |
| July 2009 | • Indian Patent Office |
| Oct 2009 | • German Patent Office |
| Nov 2009 | • USPTO |
| Feb 2010 | • UK Patent & Trademark Office |
| Sept 2010 | • Canadian IP Office |
| Jan 2011 | • IP Australia |
| April 2011 | • Japan Patent Office |

TKDL Success against Bio-Piracy attempts of MNCs



USA

| | | |
|---|------------------------------|--|
| 1 | Natreon Inc | |
| 2 | Jan Marini Skin Research Inc | |
| 3 | Phytrix JV, LLC | |

Great Britain

| | | |
|---|-------------------|--|
| 1 | GW Pharma Limited | |
|---|-------------------|--|

Netherlands

| | | |
|---|--------------|--|
| 1 | Unilever N.V | |
|---|--------------|--|

Italy

| | | |
|---|--------------------------|--|
| 1 | Data Medica Padova S.p.A | |
| 2 | Indena S.p.A | |
| 3 | Bios Line S.p.a | |

Brazil

| | | |
|---|-------------------|--|
| 1 | Acha Laboratories | |
|---|-------------------|--|

Cyprus

| | | |
|---|-----------|--|
| 1 | Bionature | |
|---|-----------|--|

Korea

| | | |
|---|---|--|
| 1 | Purimed Co., Ltd | |
| 2 | Seoul National University Industry foundation | |

Canada

| | | |
|---|-----------------------------|--|
| 1 | Herbal Infusion Corporation | |
|---|-----------------------------|--|

Israel

| | | |
|---|--------------|--|
| 1 | Naveh Pharma | |
|---|--------------|--|

Courtesy CSIR

TKDL Success against Bio-Piracy attempts of MNCs



India

| | | |
|---|---------------------------|---|
| 1 | Avesthagen Limited |  |
|---|---------------------------|---|

Norway

| | | |
|---|-----------------------------|---|
| 1 | Biotec Pharmacon ASA |  |
|---|-----------------------------|---|

Switzerland

| | | |
|---|------------------|--|
| 1 | NESTEC SA |  |
|---|------------------|--|



USA

| | | |
|---|--|---|
| 1 | Integrated Botanical Technologies |  |
| 2 | Mary Kay Inc |  |
| 3 | Apptec Inc |  |
| 4 | Tower Laboratories |  |

Australia

| | | |
|---|------------------------|--|
| 1 | Natbio Pty Ltd. |  |
|---|------------------------|--|

Korea



| | | |
|---|---------------------|---|
| 1 | UNHWA CORP |  |
| 2 | DONG-A PHARM |  |

Japan

| | | |
|---|--|---|
| 1 | MORINAGA MILK INDUSTRY CO., LTD |  |
|---|--|---|


Courtesy CSIR

TKDL Success against Bio-Piracy attempts of MNCs

| Japan | | |
|-------|---------------------|---|
| 1 | Mercian Corporation |  |
| 2 | KAO CORP |  |

| Germany | | |
|---------|---------------------------|---|
| 1 | Cognis IP Management GmbH |  |
| 2 | Evonik Goldschmidt GmbH |  |

| China | | |
|-------|--------------------------|---|
| 1 | Livzon Pharmaceutica |  |

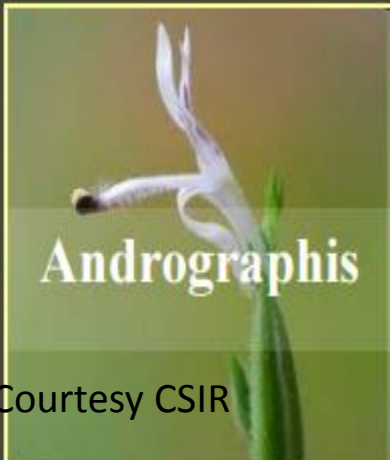
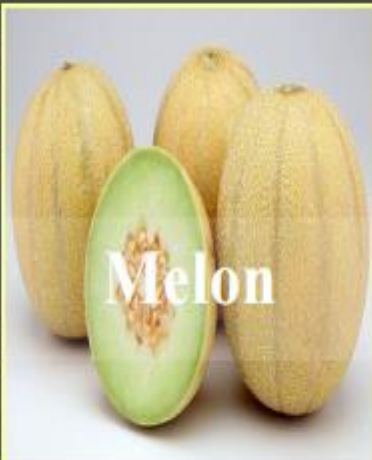
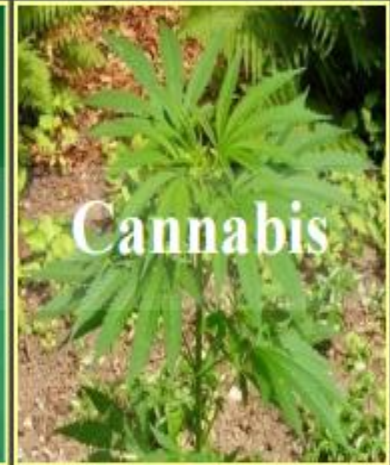
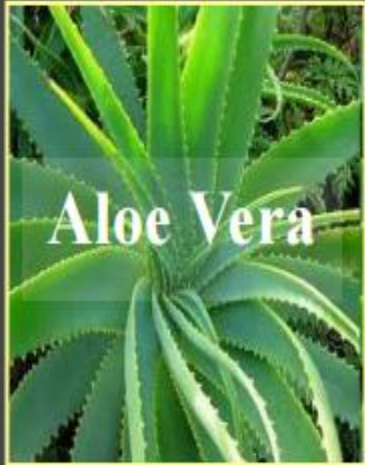
| USA | | |
|-----|-------------------|---|
| 1 | Berkson, Lindsey, |  |

| USA | | |
|-----|-------------------|---|
| 1 | Juice Beauty |  |
| 2 | Johnson & Johnson |  |

Courtesy CSIR

TKDL Out-Comes Against Bio-Piracy

Successfully safeguarded Bio-piracy attempts to patent Medicinal Plants (usages)



Courtesy CSIR

Summary

IPR in TK/GR

Indian Patent Act has a provision under **Section 3(e)&(p)** accordingly mere admixtures and knowledge which in effect is a Traditional Knowledge can not be patented.

Guidelines to ascertain novelty / inventive step in Traditional Knowledge based patent applications issued by CGPDTM

Using TKDL access, approximately 220 applications for patents (India/foreign) have either been withdrawn or refused.

1 patent has been revoked by Central Government under Section 66 of Patents Act, 1970.

Way ahead.....

- Request to participating countries to adopt TKDL as a Model for Protection of Traditional Knowledge in their respective countries
- Support at international forum to get TKDL included as PCT minimum documentation to prevent bio-piracy and misappropriation.
- Information stored in a database can be used as prior art citable for novelty and/or inventiveness to prevent patents, based on claims to old and known GRs/TK, from being granted, provided that the relevant database entries are dated and publically available.

Way ahead

- To date, a number of TK-related databases have been identified (see WIPO/GRTKF/IC/3/6 Annex II).

Considering that

- (1) in patent examination, it is necessary to search for prior art worldwide to ensure the principle of universal novelty, and
- (2) that TK associated with GR has been uniquely developing in each country/region, those databases which may be created by interested countries by collecting information on GR/TK in their countries and made available for examiners in and outside the countries, would improve efficiency and completeness of prior art searches.
- This enables examiners to make the right judgments in terms of determining whether or not an invention lacks novelty and inventive step with relevant prior art information at hand.

**TKDL has made unparalleled
Contributions to the international policy
context of the patent system and it
offers a valuable template for others**

**Dr. Francis Gurry
Director General
World Intellectual Property
Organization, Geneva
05-Jan-2009**



THANK YOU