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

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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.”

Courtesy CSIR
### Use of Traditional Medicines

<table>
<thead>
<tr>
<th>Populations using traditional medicine for primary health care</th>
<th>Ethiopia</th>
<th>India</th>
<th>Rwanda</th>
<th>Tanzania</th>
<th>Uganda</th>
</tr>
</thead>
<tbody>
<tr>
<td>Populations in developed countries who have used complementary and alternative medicine at least once</td>
<td>Canada</td>
<td>Australia</td>
<td>France</td>
<td>USA</td>
<td>Belgium</td>
</tr>
<tr>
<td></td>
<td>90%</td>
<td>70%</td>
<td>70%</td>
<td>60%</td>
<td>60%</td>
</tr>
<tr>
<td></td>
<td>70%</td>
<td>48%</td>
<td>49%</td>
<td>42%</td>
<td>31%</td>
</tr>
</tbody>
</table>

Courtesy CSIR
## Status of Indian System of Medicines

<table>
<thead>
<tr>
<th>System of Medicine*</th>
<th>Registered Practitioners</th>
<th>Hospitals</th>
<th>Dispensaries</th>
<th>Colleges</th>
<th>Graduates Annual</th>
<th>Post-Grads Annual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ayurveda</td>
<td>3,66,812</td>
<td>2189</td>
<td>14252</td>
<td>154</td>
<td>6300</td>
<td>437</td>
</tr>
<tr>
<td>Unani</td>
<td>40748</td>
<td>189</td>
<td>966</td>
<td>31</td>
<td>1252</td>
<td>55</td>
</tr>
<tr>
<td>Siddha</td>
<td>12911</td>
<td>204</td>
<td>357</td>
<td>2</td>
<td>150</td>
<td>24</td>
</tr>
<tr>
<td>Naturopathy</td>
<td>402</td>
<td>21</td>
<td>55</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>420873</strong></td>
<td><strong>2603</strong></td>
<td><strong>15630</strong></td>
<td><strong>187</strong></td>
<td><strong>7702</strong></td>
<td><strong>516</strong></td>
</tr>
</tbody>
</table>

*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

Courtesy CSIR
<table>
<thead>
<tr>
<th>Year</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2000</td>
<td>4896</td>
</tr>
<tr>
<td>March 2003</td>
<td>15000</td>
</tr>
<tr>
<td>December 2005</td>
<td>35587</td>
</tr>
<tr>
<td>December 2008</td>
<td>85000</td>
</tr>
<tr>
<td>Medicinal Plant Patents / Year</td>
<td>5000</td>
</tr>
<tr>
<td>Possible Patents concerning Indian Plants / Year</td>
<td>4000</td>
</tr>
<tr>
<td>Possible Patents on Indian system of Medicine on yearly basis</td>
<td>2000</td>
</tr>
<tr>
<td>Annual average Growth Rate between 2000-2008</td>
<td>200%</td>
</tr>
</tbody>
</table>

Courtesy CSIR
Protecting TK and GR in India Multi-pronged strategies

- Accession to Treaties administered by WIPO
- Indian Legislations relating to protection of Traditional Knowledge and Biodiversity
- Digital Protection of Knowledge (TKDL)
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


- **Discussions under IGC**
### National legislations

<table>
<thead>
<tr>
<th>National Legislation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biological Diversity Act 2002</td>
</tr>
<tr>
<td>Protection of Plant Varieties and Farmers' Rights Act</td>
</tr>
<tr>
<td>The Patents Act 1970</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Discipline</th>
<th>No. of texts (including volumes) used for transcription</th>
<th>Transcribed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ayurveda</td>
<td>75 books</td>
<td>97,337</td>
</tr>
<tr>
<td>Unani</td>
<td>10 books</td>
<td>1,75,150</td>
</tr>
<tr>
<td>Siddha</td>
<td>50 books</td>
<td>23,016</td>
</tr>
<tr>
<td>Yoga</td>
<td>15 books</td>
<td>1,680</td>
</tr>
<tr>
<td>Total</td>
<td>150 books</td>
<td>2,92,662</td>
</tr>
</tbody>
</table>
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

Ayurveda
91,410

Unani
1,29,170

Siddha
15,290

Yoga
1,305

Total documents
0.292 Million

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

### Italy
1. Data Medica Padova S.p.A
2. Indena S.p.A
3. Bios Line S.p.A

### Korea
1. Purimed Co., Ltd
2. Seoul National University Industry foundation

### Great Britain
1. GW Pharma Limited

### Brazil
1. Acha Laboratories

### Cyprus
1. Bionature

### Netherlands
1. Unilever N.V

### Canada
1. Herbal Infusion Corporation

### Israel
1. Naveh Pharma

Courtesy CSIR
TKDL Success against Bio-Piracy attempts of MNCs

**India**
1. Avesthagen Limited

**Switzerland**
1. NESTEC SA

**Korea**
1. UNHWA CORP
2. DONG-A PHARM

**USA**
1. Integrated Botanical Technologies
2. Mary Kay Inc
3. Apptec Inc
4. Tower Laboratories

**Norway**
1. Biotec Pharmacon ASA

**Australia**
1. Natbio Pty Ltd.

**Japan**
1. MORINAGA MILK INDUSTRY CO., LTD

Courtesy CSIR
## TKDL Success against Bio-Piracy attempts of MNCs

### Japan

<table>
<thead>
<tr>
<th>Rank</th>
<th>Company Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mercian Corporation</td>
</tr>
<tr>
<td>2</td>
<td>KAO CORP</td>
</tr>
</tbody>
</table>

### Germany

<table>
<thead>
<tr>
<th>Rank</th>
<th>Company Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cognis IP Management GmbH</td>
</tr>
<tr>
<td>2</td>
<td>Evonik Goldschmidt GmbH</td>
</tr>
</tbody>
</table>

### China

<table>
<thead>
<tr>
<th>Rank</th>
<th>Company Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Livzon Pharmaceutical</td>
</tr>
</tbody>
</table>

### USA

<table>
<thead>
<tr>
<th>Rank</th>
<th>Company Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Berkson, Lindsey,</td>
</tr>
<tr>
<td>2</td>
<td>Juice Beauty</td>
</tr>
<tr>
<td></td>
<td>Johnson &amp; Johnson</td>
</tr>
</tbody>
</table>

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Courtesy CSIR
TKDL Out-Comes Against Bio-Piracy

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

Aloe Vera  |  Withania Somnifera  |  Brahmi  |  Ginger  |  Cannabis
Mint  |  Melon  |  Terminalia Arjuna  |  Pitavia vera  |  Andrographis

Courtesy CSIR
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