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India's Biodiversity Wealth: Global Perspectives and Benefits for India

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American BioIndustry Alliance (ABIA): Focused Advocacy for BioIndustry

- *ABIA Website*: Launched Dec 2005; now primary source of information for industry ABS views
- *ABIA Publications*: Essays, positions, views gain coverage from major trade journals and on-line pubs
- *ABIA Events*: Provide educational information at multilateral events, and in key capitals.
- *Survey of Developing Country Delegates*
-- ABIA is an important, reliable source of information: “that provides a counterview on disclosure of origin for genetic resources.”
NGOs, Intellectual Property Rights and Multilateral Institutions,
Duncan Matthews, December 2006, pp. 14 and 28

What is at Stake

- Biodiversity Regime limits Indian Biotechnology Industry:
 - Mandatory patent disclosure and “Law of Unintended Consequences;” weak incentives for conservation, reduced investment in innovative GR/TK
- Dilution of biotechnology patentability: Biological Diversity Act (2002), Regulations (2004) restrict genetic resource patent rights:
 - creates major hurdles for researchers,
 - researchers have to bio-prospect without Indian rights,
 - could cloud patent rights gained abroad,
 - no national treatment, and
 - track record of bureaucratic inertia
- Related patent law provisions provide additional grounds to challenge, revoke patents

India 2nd Patents Amendments, Biological Diversity Act

- **2002 Patents (Amendments) Act**
 - “Every complete specification shall... disclose the source and geographical origin of the biological material in the specification, when used in an invention.”
(2002 Patents (Amendment) Act)
 - Two new grounds for revocation:
 - “The complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention.”
 - “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.”
- **2002 Biological Diversity Act**
 - Requires all inventors to obtain consent of National Biodiversity Authority (NBA) before applying for access, technology transfer, & patents, where the invention is based on any biological resource (broadly defined)
 - Grants NBA power to impose benefit sharing fee or royalty or to impose conditions, including sharing of financial benefits arising out of commercial utilization of such rights

Indian Innovation Bypasses GR/TK

- Contrast: India's FDI/Clinical Research growth
 - Record growth in knowledge-intensive sectors
 - Top-5 countries as R&D destination (Ernst and Young European Attractiveness Survey 2006)
- Commercial biotech \$2B in 2007; 36% growth
- GR/TK limitations harm Indian biotech
 - MNCs active in pre-clinical, clinical pharma R&D; little FDI in GR/TK
 - Indian companies also focus on pharma R&D

Compare Growth of Traditional Chinese Medicine (TCM) Research

- Chinese Patent Law provides full GR/TK patent rights
- Domestic and multilateral research
 - Long-term research by China Institute of Medicinal Plant Development (IMPLAD): includes R&D, JVs, patenting and commercial drug development; more than 1,000 papers and 30 monographs.
 - New Ministry of Science and Technology 100M Yuan Initiative
 - International research partners: WHO, U.S., France, Germany, Japan, and Singapore, et al.
- International Private R&D Partnerships: Merck KGaA, Merck (US) Novartis, Pfizer, others

TCM Shows India's GR/TK Potential

- Chinese Government TCM Policy:
 - Full patent rights for GR/TK
 - Protects patrimony and promotes commercial drug development.
- Major therapeutic categories: Oncology, HIV/AIDS, CNS, Malaria, Auto-Immune disorders, Respiratory

- Promise of New R&D Pipeline:

“[T]raditional Chinese medicine is a major, under-exploited reservoir for the development of novel drugs for the global pharmaceutical market.”

Pharmaceutical Business Review Online, November 20, 2006

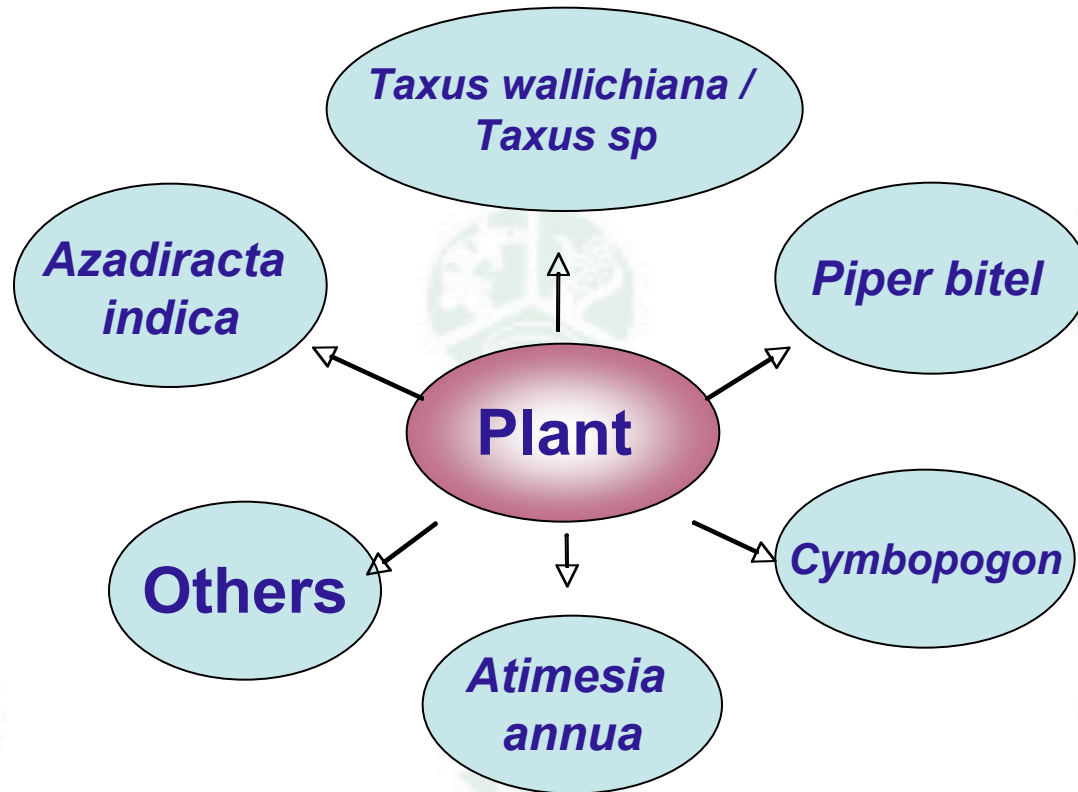
Indian Biodiversity Second to None

- Internationally recognized as mega-diverse:
Two of the world's 25 bio-diversity “hot spots”
 - 26 recognized endemic centers, home to nearly 1/3 of flowering plants identified and described.
 - More than 50,000 varieties of rice, over 5,000 varieties of sorghum, 1000 varieties of mango and as many as 500 varieties of pepper.
 - Center of origin of 30,000-50,000 varieties of rice, pigeon-pea, mango, turmeric, ginger, sugarcane, gooseberries, etc.
- Centuries old tradition: Ayurveda, Siddha, Unani, Yoga, Naturopathy and folklore medicine
- Documented in the TK Digital Library (TKDL)

Indian Leadership on TKDL

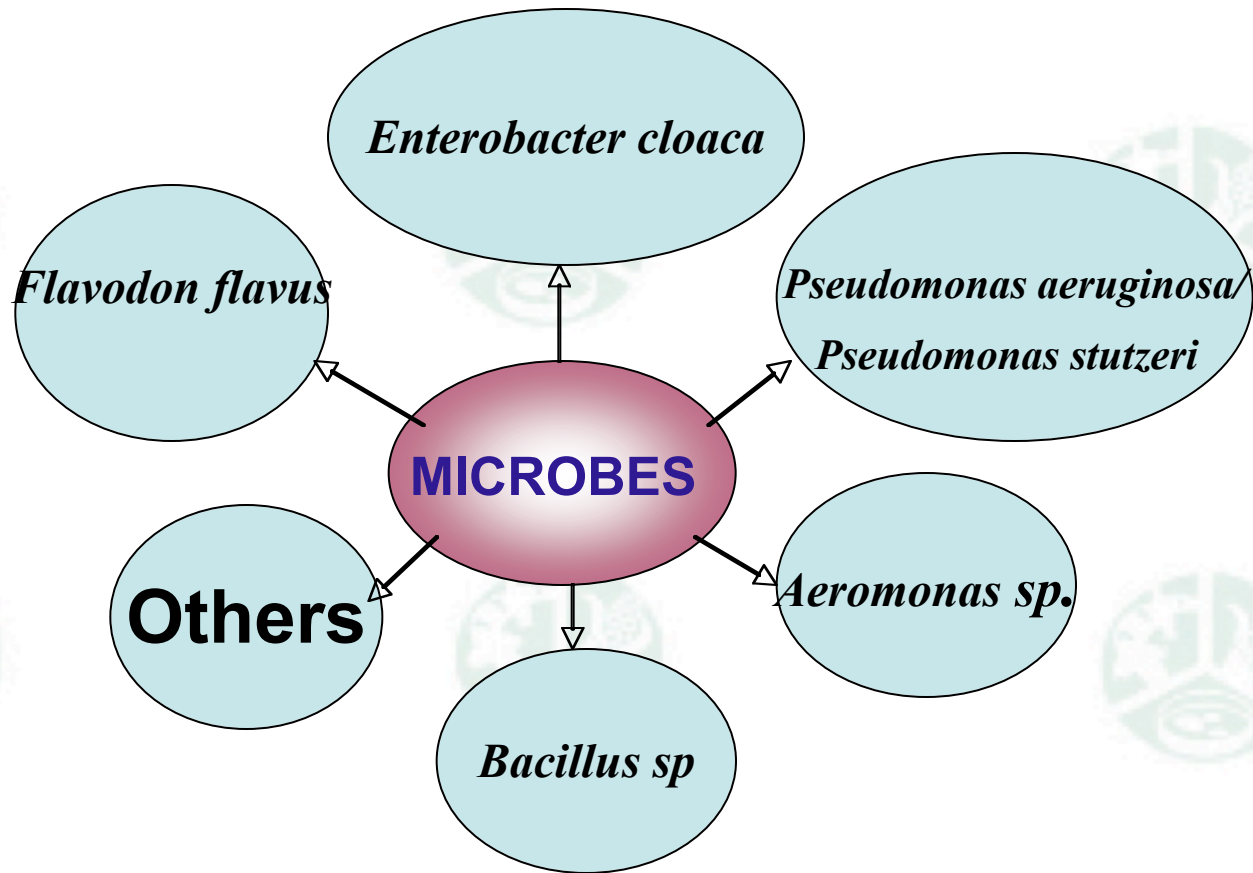
- Traditional Knowledge Digital Library (TKDL) provides documentation of all prior art associated with Indian biodiversity.
- Recent India/U.S. agreement assures patent office review of prior art in India when reviewing patent applications.
 - prevents issuance of patents based on prior art;
 - no reoccurrence of turmeric-type patents in recent years (even before recent TKDL MOU).

Major Plants



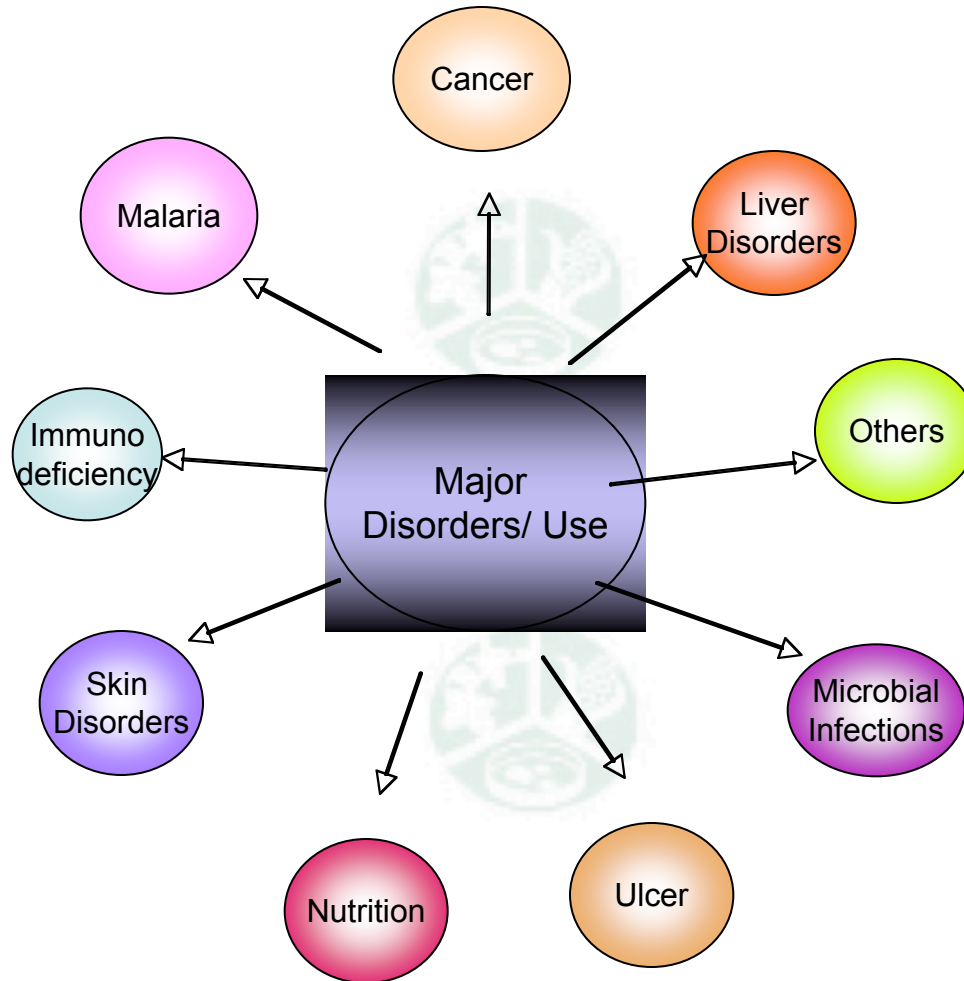
“Others” include: *Saraca indica*, *Emblica officinalis*, *Terminalia sp.*, *Zingiber officinale*, *Cyperus rotundus*, *Pterocarpus santalinus*, *Berberis aristata*, *Cuminum cyminum*, *Adhatoda vasika*, *Nelumbo nucifera*, and *Piper longum*, *Rheum emodi*, *Phyllanthus amarus*, *Eclipta alba*, *Andrographis paniculate*, and *Picrorhiza kurroa*, *Fumaria officinalis*, *Tinospora cordifolia*, *Cichorium intybus*, *Tephrosea purpurea* and *Boerhaavia diffusa*

Major Micro-Organisms



•Above identified microorganisms are mainly used for **BIOREMEDIATION**

Major Targeted Disorders or Use



Other Applications: Cosmetic applications, ointment formulations, dental creams, etc

TKDL Promotes Biodiversity Innovation

- TKDL provides millions of pages in several languages to document Indian biodiversity
 - Establishes prior art; prevents reoccurrence of patents based on India's patrimony.
 - Provides positive incentives for GR/TK R&D, to create meaningful benefits from Indian biodiversity.
- TKDL but one of a number of positive alternatives to patent disclosure:
 - Others include capacity building, technology transfer & milestone payments/royalties.

Conclusion

- Indian biodiversity holds same or greater promise as TCM
- Weakening of biotech patentability standards through patent disclosure undercuts investment and innovation in Indian GR/TK
- TKDL and other alternatives promote biodiversity, conservation, sustainable development and provide meaningful benefits consistent with growth of India's biotechnology industry.

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