Biological Diversity Act 2002, Research & the ABS



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What We Know Is Not Important, What We Need To Know Is Important.



Possibility of Commercialization

Why do research?

Conservation

Research

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Innovation

Ξ

Scalable

Science – Generate new knowledge

Innovation – Emphasis on product development & pathway to commercialization

Regional Impact – sustainable and scalable social and economic benefits







Does BD Act Affects Research?

- Indian researchers not required to seek permission from NBA for obtaining bio-resources for carrying out research but should inform SBB prior to undertaking research.
- NRIs, foreign national / agencies not registered or registered in India who wants to access our bio-resource or associated TK for research, commercial utilisation, bio-survey and bio-utilization, seek permission (Section 3). NBA reserves the right to deny approval [Section 19(3)].

What BD Act 2002 Says?

- When the result of the research relating to bio-resources of the country are to be transferred to the foreigner, NRI or foreign companies for monetary benefit (Section 4).
 - > [Transfer does not include research publications or dissemination of knowledge in seminars or workshops].
- When Patent and Intellectual Property Right is sought on Indian bio-resources [Section 6(1)].
 - > [NBA reserves the right to deny approval [Section 19(3)]; while granting approval, NBA may impose benefit sharing fee or royalty fee or both or impose conditions for sharing of financial benefits arising out from the utilization of such rights [Section 6(2)].
 - > Benefit sharing can be anything; namely,
 - Joint ownership of IPR with NBA or benefit claimers
 - Transfer of technology

What BD Act 2002 Says?

- Establishment of production, research and development units in the area of source
- Involvement of the Indian Scientists, benefit claimers and local people with research and development (applicable for foreign companies)
- Setting up venture capital fund for helping benefit claimers
- Payment of monetary compensation or non-monetary benefits to benefit claimers
- > NBA further reserves the right to oppose the grant of IPR in any country outside India on any bio-resources or knowledge associated with it [Section 18(4)].

What BD Act 2002 Says?

- This Act shall not apply to person making application for protection of plant varieties enacted by Parliament [Section 6(3)].
- When the result of the research is used for commercial purpose, SBB needs to be intimated (Section 7).
- SBB, after consulting the respective BMCs, may or may not grant approval if it is of the opinion that the activities violates the objectives of the BD Act [Section 24(2)].
- If approval is granted, it is the responsibility of the research institutions to coordinate with the SBB in further ABS process.
- SBB can revoke the approval granted for access to bioresources at any time (Rule 15).
- **⊙** No suit, prosecution or legal proceedings lies against the Authority / Board, if the decision is taken under the Act / Rules (Section 54).

Research and bio-piracy

Bio-piracy: Misappropriation and commercialization of the genetic resources and the TK of the indigenous people without their consent or PIC (Prior Informant Consent).

Bio-piracy operates through unfair application of patents to genetic resources and traditional knowledge in the name of bioprospecting.

Initially, patent and IPR were the mode of rewarding innovation and knowledge and was associated with the field of industrial invention, art and literature; now is applicable to agricultural and biological inventions.





Research and Bio-piracy

- As per Article 52(2) (a) of European Patent Convention "discoveries...as such discoveries) are not regarded as inventions".
- Patent based on TK is illegal because it does not acknowledge the principles of novelty or inventiveness; it is a mere discovery and not invention.
- Cosmetics, pharmaceuticals and agro food firms are the main pirates of bio-resources / genetic resources.
- Bio-piracy is not only the piracy of the natural resources but also the theft of the economic development opportunities

Bio-piracy: India's experience



India foils Danish firm's bio piracy bid

New Dellit: After stooping the Chinese from patenting pudina's health benefits, india has now totled a major bio piracy bid by a Danish company to patent eincen teera (cumin), ontonand comeric's fal-burning properties.

Claras Ap8, a Danish company on September 19, 2007 filled a patent application at the European Patent Oflice, saying its invention of turnerto, current, gauger and outon as sitmming agents was novel. But the Council of Scientific and Industrial Research (CSIR), with the help of India's Traditional Knowledge Digital Library (TKDL), dug our formulations from prejent Ayurveda mets dating back to the ath century, which contained formulations involving their use for ages in Irulia, as fat burners.

Director of TKDL V K Gupta sub mitted a letter to EPO on August 25, withdraw its patent and claims. Ac-2009 to inform the examiners that all the four bave long been known in indian systems of traditional medicine for their use as adminime agents or faldestroyers. CSBC's letter to EPO said. - timated that about 2,000 wrong patents "The patent application number—concerning Indian systems of medi-EP2044650, titled method for affering — this were being granted every year. the metabolism characteristic of food — mainly due to the fact that India's medproducts, may be referred to wherein - home knowledge existed in languages usefulness of a herbal composition of — such as Sansiari, Hindi, Arabic, Urdu. Zingiber officinale (ginger), Allfun - Tanui etc and was neither accessible ceps (onton). Cuminum cyminum por understood by patent examiners

Claras ApS, a Danish company, filed a patent application in 2007 at the European Patent Office. saying its use of turmeric, cumin, ginger and onion as slimming agents was novel

(comin seed) and Concorns longs iturmerica on being added to a food product as a slimming agent by after ing dignistion characteristic/metaboliam characteristic of the food prodget has been daimed to be novel.

The letter was accompanied with evidence from ago old Indian medicinal texts, "Following India's intervention, the Danish company was not left with any option except to cordingly, the company decided to tion," a health ministry official said.

In 2000, the TKDL expert group es-

Biopiracy in India: The case of the aubergine (brinjal)



US based biotech company, Monsanto, through its Indian subsidiary Mahyco and several agricultural universities, inserted a bacterial gene into the indigenous brinjal

genome to create a genetically modified version named BT brinjal (2005 - 2006) without entering into dialogue with local farmers of Kamataka and Tamil Nadu, who have cultivated these varieties for generations, and also the Gol (NBA). In response, the national biodiversity authority has planned to prosecute Monsanto for carrying out this research without seeking its permission and the consent of farmers.

Basmati Rice Case

US Patent Office granted a Patent (Patent No. 5663484) on Basmati Rice to Texas based company Rice Tech Inc. In September 2, 997.

India and Pakistan together joined hands to tackle the crisis against Rice Tech Inc., who were supported by UK and the Middle East countries. India threatened that US violated the Geographical Indicator Act under International Treaty on Trade Related Intellectual Property Rights (TRIPs) by granting Patent to Rice Tech Inc. and would take the matter to WTO as Geographical Indication products cannot be patented. This shuddered US Patent Office and the patent was revoked

Neem Case

In 1994, a US Department of Agriculture granted a patent to a US based company WR Grace, for a fungicide made from Neem oil. The decision was later opposed by many of the NGOs and environmental organizations considering it as 'biopiracy'. Subsequently, the patent European the withdraw agreed to 2000 May, confirming that "nothing has been invented, and that knowledge and use of Neem have been widespread in India and elsewhere for many decades"



In 1997, the US patent office revoked the patent of Turmeric (Curcuma Longa Linn.) given to the University of Mississippi Medical Center, ascertaining that there was no novelty; the findings by innovators having been in India for centuries.



India: Laws to curb bio-piracy

• The Patent Act, 1970

As per Section 3, any plants and animals in whole or any part thereof, or any traditional knowledge not to be considered as an invention under the act. Since they are not an invention, no person can claim for the patent rights of these things.

Protection of Plant Varieties and Farmer's Right Act, 2001

The act recognizes the role of farmers as cultivators and conservers and the contribution of traditional, rural and tribal communities to the country agro-biodiversity by rewarding those for their contribution through benefit sharing and protecting the traditional rights of the farmers.

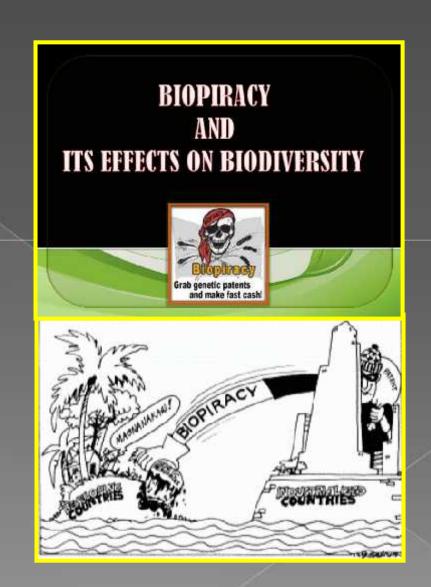
- Geographical Indication of Goods (Registration and Protection) Act, 2003
 - GIG Act, 2003 is a sui generis legislation enacted by union government of India, with an aim to protect the geographical indications of the country. Under this act a product is defined by a geographical area where it is traditionally found. It also advance product standards, provide cataloguing and categorization and enforces regulation.

Darjeeling tea became the first GI tagged product in India, in 2004–05

- O Setting up of Traditional Knowledge Digital Library (2001) to fight bio-piracy and unethical patent.
- Repository of 1200 formulations of various systems of various systmens of Indian medicines viz., Ayurveda, Unani and Siddha.
- 50 traditional ayurveda books digitized and available online.

How the BD Act checks bio-piracy?

- Access to bioresources is subject to terms and conditions which secures equitable sharing of benefits.
- NBA's approval is required before seeking IPR based on bio-resources and associated TK from India



Issues in Sikkim

- Bio-piracy
 - > Suggestion: Every visitor to be accompanied by <u>Liaison Officer</u> from the Forest Department.
 - > SBB (FEWMD) to coordinate with the Home Department.
 - > Awareness programme for the travel agents / tour operators.
- Line Department to ensure <u>intimation</u> to the SBB, before introducing new crop varieties / animal breed.
- Single window system for research permit.
- **To have our own Traditional Knowledge Digital Library.**

Penalties: If a person, violates the regulatory provisions he will be "punishable with imprisonment for a term which may extend to 5 years, or with fine which may extend to 10 lakh rupees and where the damage caused exceeds 10 lakh rupees, such fine may commensurate with the damage caused, or with both" (Section 55). Any offence under this Act is <u>cognizable</u> and <u>non-bailable</u>.

