

**LECTURES ON "IPR" FOR SCIENCE
STUDENTS**
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By

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Dr. B.B.Singh holds a Master's degree in Physics and is a recipient of the Gold Medal for being the best student of the year. He obtained his Ph. D. degree in Radiation Biology from the university of London and is an elected Fellow of the Indian Academy of Sciences and also of the National Academy of Sciences of India. He has been awarded the degree of Doctor of Sciences (h.c.) from the International Open University, Colombo, Sri Lanka. He had held several important positions in



India at the Bhabha Atomic Research Centre Mumbai and at the United Nations' International Atomic Energy Agency in Vienna. He has served as an expert in various countries including at the Syrian Atomic Energy Commission, Damascus. He is a scientist of international repute specializing in the fields of free radical biology and combination therapy of cancer with radiation and hyperthermia. He is a widely traveled scientist and has participated in 44 international conferences in over 32 countries and has been a member of the Organizing Committee of numerous international conferences held in India and abroad. He has to his credit 2 books and 163 original scientific papers published in as reputed scientific journals as *Nature* (Lond.) and *Science* (Wash.). He has been the President of Indian Biophysical Society, Indian Society for Radiation Biology and Indian Association for Hyperthermic Oncology & Medicine and a Hon. Member of International Society for Clinical Hyperthermia. He retired in 1998 as the Head of the Biochemistry and Radiation Biology Divisions of Bhabha Atomic Research Centre, Mumbai, India. He has served on the Editorial Boards of several International Journals including Intl. J. Radiat. Biol. (UK); Intl. J. Hyperthermia (UK); Radiation Phys. & Chem. (UK).

Dr. Singh also holds LL.B. degree from the Mumbai University specializing in Environmental Law and Consumer Protection. His research work at the J.C. College of Law, Mumbai on "Laws Relating to IPR in Biomedical Technologies in India" has earned him the degree of LL.M. from the Mumbai University. He has been a Research Fellow at the Institute of Intellectual Properties, University of Tokyo, Japan and is currently a member of the Editorial Board of the Intl. Journal of Nuclear Law (Paris). He is presently practicing at the Bombay High Court on laws relating not only to IPR issues but also in other branches of law such as Constitutional remedies & Writs, Public Interest litigations, Consumer Protection, Recovery of debts, Company matters including mergers and winding-up, arbitrations and conciliations, transfer of properties and cases complicated by Indian personal laws for child adoption and matrimonial disputes.

He has extensively toured India for over 5 years delivering public lectures on fallacies of the Indian Patent Bill before it was passed into an Act by the Parliament. He is an active member of several NGOs and social welfare bodies including Rotary International, Masonic Fraternities and Swadeshi Jagran movement. He is a very popular public speaker and a teacher for students of academic pursuits and has guided several research scholars for their master and doctoral degrees in various Universities.

LECTURE - 6
BIODIVERSITY
AND
PROTECTION OF PLANT BREEDERS RIGHTS AND
FARMERS RIGHTS

Introduction

It all started at the end of the IIInd. World war that the British Government wanting to ensure that seed used for agricultural production was of high quality, it instituted a system for registering good-quality seed. Logically seed companies were then required to sell only registered seed. Soon after that, the British Government thought of rewarding individuals who improved seed further, and it gave them the legal right (Breeders' Right) to levy royalties on the sale of new seed varieties they bred. This worked well for some years.

But soon, four developments took place, originating from the desire to control the market that distorted the system.

- 1) The royalties became insignificant compared to the expense incurred in industrial espionage and in legal fees so that only big companies which wanted to control the market, rather than individual inventive minds, became the beneficiaries. For example, preparing a US patent application is said to cost US\$40,000. Litigation to prevent infringements on patents costs even more than this.
- 2) Particularly in seed production and marketing, the seed companies, initially slowly but later on blatantly, dropped good seeds that were not IPR-protected and focused only on IPR-protected seeds, again in order to control the market. Of course, the companies promoted their own seeds, or seeds that were under royalty-sharing arrangements with IPR holders. Seed production, therefore, moved from the hands of the farmer to the corporations.
- 3) Breeders' Rights laws became more and more restrictive until the 1991 version of the Union for the Protection of New Varieties of Plants (UPOV) became very similar to patent law.
- 4) Perhaps because the restrictive Breeders' Rights laws prepared the ground, the patenting of living things became accepted, first in the USA, and then in Europe.

The companies can force their technologies on farmers because, over decades, the European and American and even many developing country farmers have lost their traditional varieties and are thus entirely dependent on the seed these corporations bring to the market.

The standard method for making the farmers so completely dependent is by providing them with cheap seed and agrochemical inputs until they lose their traditional systems of seed supply, soil fertility, and pest and disease management systems, and then raising the price of seed and agrochemicals to profitable levels, including to levels sufficient for recouping previous subsidies.

The industrialized world now sees biodiversity as a raw material. It gives them traits which their modern biotechnology or genetic engineering and related recent biomolecular manipulation techniques can use in various combinations in microbial, plant or animal transgenic varieties, or even in in vitro enzyme systems. They expect that these transgenic varieties will produce commodities they want, including food, medicines and other bioactive molecules, and chemicals which have hitherto been made through the use of cumbersome industrial plants. Of course, developing countries also aspire, and some do indeed try to, with varying degrees of success, to do the same.

The term 'biological diversity' or 'biodiversity' is commonly used to describe the number and variety of living organisms on the planet. It is defined in terms of genes, species, and ecosystems that are the outcome of over 3,000 million years of evolution. 'Biological diversity' includes diversity within species, between species and of ecosystems. The human species depends on biological diversity for its own survival. Thus, the term can be considered a synonym for 'life on Earth'.

To date, an estimated 1.7 million species have been identified. The exact number of the Earth's existing species, however, is still unknown. Estimates vary from a low of five million to a high of 100 million.

Why conserve biodiversity?

Species extinction is a natural part of the evolutionary process. Due to human activities, however, species and ecosystems are more threatened today than ever before in recorded history. The losses are taking place in tropical forests - where 50-90 per cent of identified species live - as well as in rivers and lakes, deserts and temperate forests, and on mountains and islands.

The most recent estimates predict that, at current rates of deforestation, some two to eight per cent of the Earth's species will disappear over the next 25 years. While these extinctions are an environmental tragedy, they also have profound implications for economic and social development.

At least 40 per cent of the world's economy and 80 per cent of the needs of the poor are derived from biological resources. In addition, the richer the diversity of life, the greater the opportunity for medical discoveries, economic development, and adaptive responses to such new challenges as climate change. The variety of life is our insurance policy. Our own lives and livelihood depend on it.

With only 65-70 per cent of the land area surveyed so far, India already accounts for 7-8 per cent of the recorded species of the world. Over 47,000 species of plants and 81,000 species of animals have been recorded by the Botanical Survey of India and the Zoological Survey of India respectively. It is believed that some of the remaining areas in the Himalayan region and Andaman & Nicobar Islands, may be far richer in biological diversity than most of the areas already surveyed. India is also one of the twelve primary centres of origin of cultivated plants and is rich in agricultural biodiversity.

Biodiversity, on the whole, increases towards the equator and decreases towards the poles. It is thus the industrialized Northern countries, which see themselves as masters or potential masters of modern biotechnology, that are biodiversity-poor, and the developing Southern countries, which see themselves as biotechnology-deficient, which are biodiversity-rich. It is natural, therefore, that both North and South want biodiversity conserved, that it be made accessible to the North, but that, in exchange, modern biotechnology also become accessible to all but primarily to the South. In this way, both North and South can benefit fairly and equitably. The Convention on Biological Diversity, adopted in Rio de Janeiro in 1992, was aimed at regulating this understanding.

CONVENTION ON BIOLOGICAL DIVERSITY- 1992

(05.06.1992)

Objectives:- Article 1.

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

Definitions: Article 2

"Biological diversity" means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

"Biological resources" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

"Country of origin of genetic resources" means the country which possesses those genetic resources in in-situ conditions.

"Country providing genetic resources" means the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country.

"Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.

"Genetic resources" means genetic material of actual or potential value.

"Sustainable use" means the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

THE INDIAN BIODIVERSITY ACT 2002 (18 OF 2003)

(5.02.2003)

Salient Features

Section - 8: For the purposes this Act the Central Government shall establish a body called the National Biodiversity Authority (NBA).

Section - 22: To advise the State Governments on all matters relating to Biodiversity and for regulating grant of approvals for commercial utilization of bioresources by Indians, the State Government shall appoint a Board called (----) Biodiversity Board.

Section - 3: All foreign national require approval from NBA for obtaining Biological Resources.

Section - 4: Indian individuals/entities to seek approval before transferring knowledge / research and material to foreigners.

Section - 5: For collaborative research projects involving transfer and exchange of biological resources of information relating thereto between Indian institutes and other countries Guidelines shall be provided for by the Government.

Section - 6: Prior approval of NBA before applying for any kind of IPR based on research conducted on biological material and or associated knowledge obtained from India.

Section - 7: Indians required to provide prior intimation to State Biological Boards for obtaining biological material for commercial purposes. SBB can regulate such access.

Growers and cultivators of Biological Diversity and *vaid*s and *hakims* who are practicing Indian system of medicines and local people exempted.

PROTECTION OF PLANT VARIETIES AND FARMERS' RIGHTS ACT 2001 (53 OF 2001) (30.10.2001)

Plant Breeders' Rights (PBRs)

The political opposition to extending patent protection of plants and the legal complexities of defining plant varieties, PBRs emerged with the UPOV (Union pour la Protection des Obtentions Vegetales) in 1961 as an exclusive right over the commercial production and marketing of the reproductive or vegetative propagating material of the protected variety. PBRs are less stringent than Patents since they allow for (a) the use of a protected variety in competing breeding programmes as long as their subsequently derived varieties do not require the repeated use of the protected variety for production (research exemption in Patents); and (b) the use and exchange of seeds from harvests, but not their sale by farmers (farmers' privilege).

The UPOV was amended to strengthen PBRs by including the concept of Essentially Derived Variety (ED) and making optional the farmers' privilege to save and exchange seeds.

Farmers' Rights (FR)

The US signed the Convention on Biodiversity but failed to ratify it. The biotechnology corporations did not want to be bound by the global regulation envisaged. They wanted to continue taking biodiversity from anywhere, patenting the varieties taken from the South and denying recognition to the local and indigenous communities therein who developed and provided the varieties in the first place, and who are recognized by Articles 8(j) and 10(c) of the Convention on Biodiversity. That is why, at the negotiations of the International Undertaking on Plant Genetic Resources (IUPGR) - which covers the exploration, preservation, evaluation and the making available of plant genetic resources, the US kept insisting that 'Farmers' Rights' is merely a concept.

FRs are an explicit recognition that farmers also innovate and deserve recognition and rewards just as the breeders do. The FRs are three types: (a) Farmers Privilege - to save, use and exchange but not to sell seeds without penalty; (b) Benefit Sharing - this has emerged from the Convention on Biodiversity which recognizes that genetic resources are not simply a common heritage but they are the sovereign right of nations. (c) Ownership - it is an extension of the IPR concept over the farmers' varieties.

HISTORY OF INDIA'S PLANT VARIETY AND FARMERS RIGHTS ACT 2001

- < 1980 India's seed policy restricted the role of private companies in agriculture and Public Sector has not favoured introduction of PBRs in India.

- 1985 The Seed Association of India was set up which promoted the concept of PBR
- 1988 The New Seed Policy allowed private firms entry into the seed sector.
- 1991 ICAR set-up a Committee which recommended PBR for hybrids and if extended to other varieties farmers must be permitted to use their own seeds.

CONSIDERABLE PROTESTS FROM NGO AND FARMER

- 1993 First Draft Bill to grant PBRs but providing for registration of Extant Varieties (EV) as notified in Seeds Act 1966. It also included provision on Farmers Privilege & Benefit Sharing.
- 1996 Second Draft Bill
- 1997 Third Draft Bill which included also Farmers' Ownership rights on varieties.
- 1999 Fourth Draft Bill referred to Joint Parliamentary Committee (JPC) to gather views from all sectors.
- 2000 JPC presented the Fifth Draft Bill which included Farmers' right as plant breeders and contained 2 mechanisms for conferring rights to farmers. Firstly definition of extant variety was expanded to include farmer's varieties, varieties in public domain and varieties about which there is common knowledge and secondly registration of farmer's variety was added.

30.10.2001 Act was passed by the Parliament

SALIENT FEATURES

This is a unique Act and a model for the rest of the Developing countries as it takes care of the native farmers and at the same time of multinational plant breeding companies.

IPR can be claimed over 4 types of varieties

New Variety (NV)- It must have the characteristics of novelty, distinctiveness, uniformity and stability. Rights granted are for 9 yrs and

renewable for 18 years for trees and vines and for other crops
6 yrs renewable for 15 yrs.

Extant Variety (EV)- As defined under the Seed Act 1966. Criteria are distinctiveness, uniformity and stability and rights are granted for 15 yrs.

Farmer's Variety (FV) - A variety which has been traditionally cultivated and evolved by framers in their fields; the criteria of distinctiveness, uniformity and stability are not clear and the period of rights granted is also not clear but it may be taken as 15 years.

Essentially Derived Variety (EDV) - A variety essentially derived from such initial variety while retaining the expression of the essential characteristics of the initial variety but is clearly distinguishable from such initial variety etc. Grant of rights and period are the same as NV.

BIOPIRACY

Biopiracy is defined as theft of indigenous knowledge which is closely linked to the local bioresources. Its implications can be easily appreciated with the "turmeric case".

In 1995, two U.S. based Indians were granted the U.S. Patent No.5,401,504 on "Use of Turmeric in Wound Healing" which was assigned to the University of Mississippi Medical Centre, U.S. The invention claimed was the use of turmeric at the site of an injury and/or its oral intake to promote the healing of a wound.

This news was greeted with disbelief and surprise by most people in India because from time immemorial turmeric has been traditionally used in India for its many special properties in wound-healing and for other purposes. It is also used as an essential ingredient in cooking of many Indian dishes. How could someone obtain a patent - effectively, an exclusive right to sell and distribute something that was so commonly known to Indians? The media coverage of the patent generated debate and discussion on the issue and luckily, the Council for Scientific and Industrial Research (CSIR) under the Department of Science and Technology (DST), Government of India, decided to file application for re-examination of the patent at the USPTO. However, the challenges before the Government were many since as per the requirements of U.S. law, it was necessary to find adequate evidence in the form of printed and published information that would establish that the manner of use of turmeric as in the claimed invention, was known before the patent was claimed and, therefore, the patent was invalid. This proved very difficult despite the fact that the use of turmeric was known to every Indian household for ages. Fortunately, 32 references could be located, some of which were in the languages of Sanskrit, Urdu and Hindi. Finally, the USPTO revoked the patent.

Neem Patent

The patents on fungicidal properties of neem products jointly owned by the multinational company W.R.Grace and US Agricultural Department were challenged by Neem Campaign at the Munich-based European Patenting Office and were evoked but numerous patents on its medicinal properties are still valid.

The biopiracy list is long and includes patents taken out by New York University for anti-diabetic formulations derived from karela (bitter gourd).

HOW TO COUNTERACT BIOPIRACY

DOCUMENTATION:

(a) Central Government Activities

(i) Department of Science & Technology (DST) & IIM Ahmedabad:

Constituted National Innovation Foundation in 2000 to register and support grassroots innovations.

(ii) Indian Council of Agricultural Research (ICAR):

Mission Mode Project on Collection, documentation and validation of indigenous knowledge to document and register traditional knowledge.

(iii) Council of Scientific and Industrial Research (CSIR):

Developing International Library on traditional knowledge

(b) State Governments and NGOs

(i) Andhra Pradesh:

Villagers have prepared Community Biodiversity Registers containing community and individual knowledge of occurrence, practices of propagation, sustainable harvests and conservation, and economic uses of the local biodiversity resources. The information in the Register can be used and distributed only with the consent of the local community gram panchayat which can refuse access to the register and/or set conditions under which access would be allowed. The community can charge fees for access to the Register and can also arrange collection of biological resources and equitably disbursing the funds thus generated among the village community. However, effective control of such activities can be achieved only through legal machinery which unfortunately does not exist yet.

(ii) Karnataka,

Some NGOs have been active towards initiating and completing Peoples' Biodiversity Registers (PBRs).

Through the efforts of the Centre for Ecological Sciences, Indian Institute of Science, Bangalore, 75 Plant Biodiversity Registers had been established in ten States, by mid 1998. Drawing on the experience, the Biodiversity Register Programme evolved further at ten sites in four states along the Western Ghats region, as part of the Western Ghats Biodiversity Network. These efforts were followed in conjunction with a larger project - the Biodiversity Conservation

Prioritization Programme (BCPP). The geographical extent of the BCPP-PBR exercise was 56 sites across seven states.

(iii) Bihar, M.P. and U.P.

The Gene Campaign has undertaken documentation of biodiversity and knowledge relating thereto among three tribal populations: the Munnars in South Bihar (in the Chotanagpur region); the Bhils of Madhya Pradesh; and the Tharus of the Terai region. The educated Tribal youth have been involved in collecting data on medicinal plants and knowledge related thereto for documentation wherein the elders in the village, medical practitioners and traditional healers were consulted in the collection and understanding of the information.

(iv) Kerala,

The concern for biodiversity protection has grown dramatically in the State following disclosures in the media of the export of medicinal plant materials to a Glaxo-Wellcome company in Singapore and to the Royal School of Pharmacy in Denmark, some years ago. A premier government plant research institute was accused of clearing the exports after badly-negotiated agreements. The State government is keen to avoid making the anti-biopiracy plan an official scheme but it wants the people themselves to play the main role in policing their flora and fauna. In this activity the elected village "panchayats," will have the main responsibility.

The way is being shown in Eranalukulam where the gram panchayats have prepared a register of the district's plant and animal species. Some 8,600 trained volunteers had collected information on the various uses of the local fauna and flora in 86 villages of the district. Similar biodiversity registers have been prepared in six other districts by scientists of the Kerala Forest Research Institute.

(v) The Jaiv Panchayat (Living Democracy)

Initiated by the Research Foundation of Science, Technology and Ecology (RFSTE) in early 1999 aims to establish definitive sovereignty of local communities on their biodiversity resources. RFSTE and Navdanya have been interacting with local villagers in different parts of India (their strongest presence being in the state of Uttar Pradesh) to constitute informal community-level institutions called Jaiv Panchayats. The members of the Jaiv Panchayat comprising volunteers from a village are entrusted with the task of inquiring and recording information on biological resources, and various uses of the same in the form of Community Biodiversity Registers (CBRs). The first Jaiv Panchayat completed the CBR for Agasthyamuni village in Garhwal district, Uttranchal Pradesh on 5 June 1999. The RFSTE claims that efforts towards Jaiv Panchayats were under way in 292 sites in the country.

(vi) SRISTI - HoneyBee Network

The Society for Research and Initiatives for Sustainable Technologies and Institutions (SRISTI) based in Ahmedabad, has been involved in documenting innovation developed by individuals at the village level. The HoneyBee Network, as the initiative is called, has been documenting since 1980, not the elements of biodiversity per se, but their uses and in particular innovation surrounding these elements. It aims, through this documentation and subsequent accrual of benefits, to provide a platform through which biodiversity and local knowledge bases can be conserved.

(vii) Kalpavriksh- Beej Bachao Aandolan,

The villagers in Jardhar of the Teri Garhwal district of Uttar Pradesh now Uttaranchal, initiated an exercise in 1995 to document the various bio-resources used by the community and the conservation practices relating thereto. By mutual agreement between Kalpavriksh and the villagers, it was decided that a copy of the register would be kept in the village and another copy would be kept by Kalpavriksh, and that all the information in the register can be used and distributed only with the consent and knowledge of the villagers. The members of the Beej Bachao Aandolan (Save the Seeds Campaign) - a network of local farmers who have been involved for a number of years now in reviving and spreading indigenous crop diversity- are actively collaborating with the Kalpavriksh.

2. PROFIT SHARING

The Kani tribals in Thiruvannathapuram district, Kerala, claim that one can live for many days together without food and still be able to perform rigorous physical work simply by eating everyday a few fruits of a plant called Aarogyapaccha. Scientists from the Tropical Botanic Garden Research Institute (TBGRI), learnt about the use of this plant from the Kanis and studied the leaves of the plant which revealed that it had anti-stress, anti-hepatotoxic and immunodulatory and immunorestorative properties. Eventually, a drug "Jeevani" was formulated by TBGRI with Aarogyapaccha and three other plants as ingredients and a license to manufacture it, was given for 7 years to Arya Vaidya Pharmacy (AVP), Coimbatore, in 1995. The fee of Rs.10 lakhs was to be shared equally between TBGRI and the Kani tribals. In November 1997, some of the Kanis, with assistance from TBGRI, registered a trust called Kerala Kani Samudaya Kshema (KKSK) Trust with the objective of among others,- preparation of a biodiversity register to document the knowledge base of the Kanis, and evolving and supporting methods to promote sustainable use and conservation of biological resources. Fifty per cent of the license fee received by TBGRI has been transferred to this Trust.

GENERAL BIBLIOGRAPHY

- A. Hirai: Biotechnology & Legal Protection- Current Issues
 CASRIP Newsletter 7,3, (2001)
- ibid* **8**,1, (2001)
- Darrel G. Dotson:
 The European Controversy Over Genetic Engineering Patents
 Houst. J. Intl. Law 19, 919, (1997)
- Intellectual Property Laws (of India)
 Universal Law Publishing Co. New Delhi, (2005)
- Japan Patent Office: (CDs)
 IPR Training Text Books (1998)
 Intellectual Property Laws (1998)
- Merges R. & Nelson R.R.
 On the Complex Economics of Patent Scope
 Columbia Law Review **90**, 4, (1990)
- Martin J. Alderman, Randall R. Rader, John T. Thomas & Harold C. Wager
 Patent Laws: Publr. American Case Book Series (1998)
- P. Narayanan
 Patent Law: Publr. Eastern Law House New Delhi (1998)
- R. Ford
Europe The Morality of Biotech Patents: Differing Legal Obligations in
 Eur. Intell. Prop. Rev. **19**, 315 (1997)
- Thomas J. Kowalski
 Analysing the USPTO's Revised Utility Guidelines
 Nature Biotechnology, **18**, 349, (2000)