

BIOPIRACY: “Monopolizing Natural Resources”

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INTELLECTUAL PROPERTY RIGHTS LAW-I

BIOPIRACY: MONOPOLIZATION OF BIOLOGICAL RESOURCES

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INTRODUCTION

The Third World Countries of the South form the most biologically diverse and genetically rich part of the world. There are innumerable examples of medicinal plants, food crops and other living things found in these Countries that possess characteristics like strength, immunity and curative qualities, which when commercially exploited would get huge profits. The Transnational Corporations and other giant Companies have realized this fact and are now racing with each other to manufacture pharmaceutical and agricultural products, the main ingredients of which are genetic materials of living things ranging from soil microorganisms to animals and from food crops to genes of indigenous people. These companies are rushing to apply to patent the new products containing the collected genetic materials, so as to prevent competitors from using them. This scramble of Corporations for getting patents on biological products or what is termed by Martin Khor in his article "*A worldwide fight against biopiracy and patents on life*"¹ as 'Gene Rush' poses a substantial threat to local communities and indigenous people as they may, in future, have to pay high prices for materials, which in the first place they had after all developed. This phenomenon has come to be termed as "Biopiracy" which means not only the smuggling of diverse forms of flora and fauna, but mainly the appropriation and monopolization of traditional population's knowledge and biological resources. Often in the process of biopiracy the contribution of the indigenous people who have developed the concerned biological product is ignored and goes unrewarded as the 'benefit sharing' system under the patenting process fails to ensure that they get a share from the derived profits.

The scope of such unfair exploitation of the biodiversity has multiplied in the recent years with the facilitation of registering international trademarks and patents as well as international agreements on intellectual property.

This paper is an attempt to evaluate the phenomenon of biopiracy through a study of cases where patents have been granted on biological material in different parts of the world and how various groups are fighting it at different levels.

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BIOPIRACY: THE LEGAL PERSPECTIVE

In earlier days there was no law regarding obtaining samples of plants, microbes, and animals by scientists and other collectors. At the most the collector was required, in some instances to obtain an informal permission from the local communities or landholders and in cases of national lands, a permit. Therefore scientists used to take specimens from anywhere in the world without any repercussions. Michael A. Gollin in his article "*Biopiracy: The Legal Perspective*"² says that "Take-and-run" describes the old approach to collecting, lately dubbed "biopiracy."

But now this is no longer the situation as the developing countries, whose flora and fauna has been ruthlessly exploited by the industrialized nations, are raising protests. The practice of *Bioprospecting*, or the search of plants that give improved crop yields or which contain substances of pharmaceutical value by the industrialized nations, is not necessarily a problem until the firms prospect without permission or expropriate the results of their investigations without payment or acknowledgement to the local people. According to Gollin there are three sources of rules for biodiversity prospecting and natural product research i.e., International laws, National laws and an professional self regulation³.

International Laws

Under the 1993 Convention on Biological Diversity, sovereign national rights over biological resources are established and the member countries are committed to conserve them, develop them for sustainability, and share the benefits resulting from the use. A fair compromise regarding sharing of natural resources is arrived at through the Access and Benefit Sharing Agreements. Under the Convention it is mandatory that the country providing the biological resources have prior information regarding what will be done with the resource, and what benefits will shared. Bioprospectors, or collectors of natural products, must get permission to collect biological materials.

National Laws

Many countries have started practicing their sovereign rights over biological resources as established under the Convention. In certain countries, under laws relating to biodiversity the

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collection or export of biological materials without obtaining permission and satisfying some other conditions is considered as poaching.

Professional Self-Regulation

Also many institutions and professional organizations have decided to implement natural products research policies for their members, and these policies have quasi-legal or contractual status.

Consequences of breaking these rules

The rules regarding informed consent and benefit sharing, if broken have very serious consequences. These are discussed as follows:

- the patents on such natural product inventions come under attack and are also cancelled if it is proved that all public knowledge about the species in question and its use are not fully disclosed.
- If a researcher removes biological material illegally from a source country, and then profits from the material, the source country or affected person could recover all or some of the profits, in a United States court, based on a theory of misappropriation and related doctrines.⁴
- Clean title to biological material now means that it was obtained legitimately, and with prior informed consent from whoever had initial control over it. If there is no clean title, the value of the material is seriously reduced. The collector of an illegitimate sample will not be able to pass it on, in turn, to collaborators, partners, or third parties in the normal course of conduct for researchers.
- If the collector refuses to share the benefits, then the access to the samples maybe denied.
- Also if a person or company comes to be known as evading the rules or as associated with biopiracy, its name will be tainted and further research possibilities will dry up. Such a Company may end up with weak patents, be exposed to equitable claims for profit-sharing, lose sources of supply, face the prospect of consumer and government boycotts, barriers to importation of biotechnology products, and other loss of market share, and may face financial penalties⁵.

⁴ legal

⁵ legal

CASES OF ATTACK ON PATENTS GRANTED ON NATURAL PRODUCT INVENTIONS

The Case of Basmati Rice

A Texas Company Rice Tec was granted patents over a hybrid rice that was crossed with traditional Indian Basmati Rice and called “Texmati” in September 1997 by the US Patent Office (USPTO). The Indian government’s Agricultural and Processed Food Products Export Development Authority (APEDA) filed for revocation of these patents on the grounds that this specie of fragrant rice has been grown for centuries in the central Indian Himalayan foothills. This application for revocation of the patent succeeded in forcing Rice Tec to withdraw four out of 20 claims. But this success is greeted with skepticism by the campaigners against biopiracy according to whom now the APEDA must quickly challenge the withdrawal and force the USPTO to either accept the entire patent application for re-examination or direct Rice Tec to withdraw its patent. This claim on Basmati rice by Rice Tec is said to be the most audacious instance of ‘biopiracy’ by Western transnational corporations and the manner in which Rice Tec established its patent demonstrates that it has ignored the contributions of local communities in the production of Basmati and that it does not intend to share the benefits.

The Case of Neem

In India, the *Azadirachta indica*, commonly known as the neem tree a symbol of Indian indigenous knowledge, is useful in many fields like medicine, toiletries, contraception, fuel, construction, fungicide etc. These qualities of the neem tree has been in use in India from time immemorial. In 1971, US timber importer Robert Larson observed the tree's usefulness in India and began importing neem seed to his company headquarters in Wisconsin. Over the next decade he conducted safety and performance tests upon a pesticidal neem extract called Margosan-O and in 1985 received clearance for the product from the US Environmental Protection Agency (EPA). Three years later he sold the patent for the product to the multinational chemical corporation, W R Grace and Co.

A challenge to the patent had been made at the Munich office of the EPO by three groups: the EU Parliament's Green Party, Dr. Vandana Shiva of the India-based Research Foundation for Science, Technology and Ecology, and the International Federation of Organic Agriculture Movements.

W R Grace's justification for patents, pivoted on the claim that these modernised extraction processes constitute a genuine innovation: 'Although traditional knowledge inspired the research and development that led to these patented compositions and processes, they were considered sufficiently novel and different from the original product of nature and the traditional method of use to be patentable.'

The European Patent Office (EPO) which administers patents under the European Patent Treaty accepted the demanded invalidation of the patent on the ground that the fungicide qualities of the neem and its use has been known in India for over 2000 years, and for use to make insect repellents, soaps, cosmetics and contraceptives.

The Case of Turmeric

In March 1995 two non-resident Indians associated with the University of Mississippi Medical Centre, Jackson, USA were granted patents on Turmeric. A challenge to revoke the turmeric patents was filed by the New Delhi-based Council for Agriculture Research (CSIR). As turmeric has been used for thousands of years for healing wounds and rashes, CSIR challenged the patent on the ground that it lacked novelty.. The US Patent Office upheld the objection and cancelled the patent. It ruled that using the popular spice for medicinal purposes was not a new "invention" but a millennial old Indian practice.

FIGHT AGAINST BIOPIRACY

Groups as diverse as religious leaders, parliamentarians and environment NGOs are intensifying their campaign against corporate patenting of living things. The following are some of the actions by various groups around the world.

LEGAL CHALLENGES:

-In March 1995, the Swiss Supreme Court, in a landmark decision, ruled that the Manzana variety of the Camomile plant may not be patented. It revoked the patent that the Swiss patent office had granted in 1988 to the German pharmaceutical company DegussaAsta Medica on its Manzana variety. The case had been brought to court by a Swiss farmer Peter Lendi, president of the Bio-Herb Growers' Association

- In February 1995, the European Patent Office withdrew key parts of a patent granted to a Belgian company (Plant Genetic Systems) and a US company (Biogen Inc.) for genetically engineered herbicide resistant plants. The patent was for plant cells made resistant to glutamine synthetase inhibitors by genetic engineering, and originally covered not only the gene which had been moved from a bacteria to various plants but also all plant cells and plants which contain the gene. After a challenge by Greenpeace, the Patent Office's Appeal Board ruled the patent may only cover genetically engineered genes and plant cells but cannot extend to a whole plant, its seeds and future generations of plants grown from the cells.

CHALLENGES BY FARMERS AND OTHER INDIGENEOUS PEOPLE

- In India, farmers' movements led by M D Nanjundaswamy of the Karnataka Farmers' Union, are campaigning against the patenting of seeds and plants and the operation of foreign grain companies in the country.
- Indigenous peoples' groups have held regional meetings in South America, Asia and the Pacific, to voice their opposition to the granting of patents to companies on plants and their genes. Also, at the UN Women's Conference in Beijing, 118 indigenous groups from 27 countries signed a declaration demanding 'a stop to the patenting of all life forms' which is 'the ultimate commodification of life which we hold sacred.'⁶

PARLIAMENT AGAINST PATENTS ON LFE FORMS

⁶ MARTINKHOR

- In March 1995, India's Upper House of Parliament forced the government to defer indefinitely a patent amendment bill to bring the Indian Patent Act in line with the World Trade Organisation's treaty on intellectual property rights. The bill would have allowed for the patenting of life forms.
- The European Parliament had also voted against the European Commission's proposed directive on 'legal protection of biotechnological inventions'

CHALLENGES BY RELIGIOUS LEADERS AND NGO's

- In May 1995, leaders of 80 religious faiths and denominations (including the Protestant, Catholic, Muslim, Hindu, Buddhist and Jewish faiths) held a joint press conference in Washington announcing their opposition to the patenting of genetically engineered animals and human genes, cells and organs.
- Environment and development NGOs have also been increasingly active. Groups like the Third World Network, RAFI and GRAIN have been carrying out educational activities and also carrying out lobbying in the Biodiversity Convention.

THE INDIAN LAW ON BIOPIRACY

In India, the need to protect the local communities and indigenous people, who have been developing and conserving the biological diversity, from being ruthlessly exploited by Transnational corporations, has been long felt. Therefore amendments were made in the Patents Act, 1970 , in the year 1999 and more recently in the year 2002. Also the Biological Diversity Act, 2002 has been brought into effect. These acts of the Legislature were made to uphold the spirit of the Convention on Biological Diversity which provides a comprehensive and internationally binding legal framework for the protection of biodiversity and for the recognition of sovereign rights of the Third World over biodiversity and its components. But unfortunately these acts promote corporate hijack of biodiversity and knowledge, as well as the patenting of life forms and have opened the door for biopiracy and biopatenting.

Let us the discuss these Acts as follows:

Patents (Amendment) Act, 1999

The 1999 Act provided for the grant of Exclusive Marketing Rights (EMRs) with regard to pharmaceuticals and food articles to those who apply for product patent in these areas pending the disposal of their patent applications. Under the amendment, these EMRs shall be granted if the applicant has obtained a product patent for that product in any other member country which is a signatory to the new GATT Agreement. The only examination before the grant of such EMRs has been restricted to the matters mentioned under Sections 3 & 4 of the Indian Patents Act. Thus a person having obtained a product patent in a member country would be almost automatically be granted Exclusive Marketing Rights (EMRs) for the sale and distribution of that product in India merely on his making a patent application in India. Though the Amendment makes a provision for the grant of compulsory licence for marketing the product in India, there is no provision made for the grant of compulsory licence for manufacturing the product in India. The Act does not provide any safeguards against biopiracy of indigenous knowledge systems and did not exempt plant-based medicines and drugs from being patented.

Patent (Second Amendment) Act, 2002

The Patent (Second Amendment) Act, 2002 was cleared by the Parliament in May 2002 under the cover of the national emergencies - the genocide in Gujarat, the spread of terrorism etc.

The amended legislation provides for changes in the scope of patentable inventions, grant of new rights, extension of the term of protection, provision for reversal of burden of proof in case of process patent infringement and conditions for compulsory licenses. There are two amendments in the definition of what is not an invention that has opened the floodgates of patenting of genetically engineered seed. First, in Section 3(i) "plants" have been omitted. According to Section 3(i), the following is not an invention: *Any process for the medical, surgical, creative, prophylactic [diagnostic therapeutic] or other treatment of human beings or any process for a similar treatment of animals or plants or render them free of disease or to increase their economic value or that of their products.* The omission of "plants" from this section implies that a method or process modification of a plant can now be counted as an invention and can hence be patented. The Second Amendment has also added a new section 3(j) which allows production or propagation of genetically engineered plants to be counted as an invention, and hence patentable. The section 3(j) excludes as inventions "*plants and animals.....including seeds, varieties and species and*

essentially biological processes for production or propagation of plants and animals”. However, the emergence of new biotechnologies is often used to define production of plants and animals through genetic engineering as not being essentially biological. Without a clear definition that all modifications of plants and animals, is essentially biological, 3(j) opens the flood gate for patenting transgenic plants. By allowing patents on seeds and plants through 3(i) and 3(j), the 2nd Amendment of the Patent Laws has jeopardised our seed and food security and hence our national security.

The Biological Diversity Act, 2002

This Act was made to provide for conservation of Biological Diversity, for the sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources and knowledge.

But unfortunately, The Biological Diversity Act, 2002, does not appropriately provide for safety measures to deal with genetic pollution, nor does it reinforce the farmers right to save seeds even though seed saving is a fundamental right of farmers and needs to be adequately protected by all IPR related legislations. Section (6) of the Act which states that no application for intellectual property rights shall be made without the approval of National Biodiversity Authority. But Section 6(3) provides an exemption which states- *The provisions of this section shall not apply to any person making an application for any rights under any law relating to protection of plant varieties enacted by Parliament.* Exemption 6(3) in the Biological Diversity Act in effect says that companies can take varieties that farmers have evolved over ages with unique traits of aroma as in Basmati, drought resistance etc., and patent the traits and qualities which are a result of farmers breeding. The Act fails to do what it was designed to do — stop Biopiracy. It has failed to recognize the legal standing of local communities and their inalienable rights to their biodiversity and collective innovation.

CONCLUSION

Many important drugs like penicillin, cyclosporin and anti-cancer drug Taxol are derived from the nature. The genetically-rich developing world are being targeted by giant corporations for getting genes of plants and animals for improved crops and for producing future drugs. In such a situation an equitable profit-sharing system should be evolved in which scientific and technological breakthrough is promoted but the contributions and rights of those who cultivate and preserve such resources should also be recognized and it should be ensured that the real custodians of genetic resources and traditional knowledge have a share in the derived benefits. Such a system will not only help developing countries fight poverty but would also provide an incentive for local people to conserve their biodiversity and would reduce the threat of over-exploitation.

The two most important criteria for the grant of patent are “novelty” and “non-obviousness”. Novelty implies that the innovation must be new. It cannot be part of 'prior art' or existing knowledge. Non-obviousness implies that someone familiar in the art should not be able to achieve the same step. Most patents based on indigenous knowledge appropriation violate the criteria of novelty combined with non-obviousness because they range from direct piracy to minor tinkering involving steps obvious to anyone trained in the techniques and disciplines involved.

The developing countries should define and interpret 'novelty' according to generally accepted concepts, namely, any prior disclosure whether written or not destroys novelty. Knowledge, like use of medicinal plants diffused within a local or indigenous community should also be deemed prior art and patent denied. And writing such a rule into their legislation would prevent patenting of knowledge or materials developed by and diffused within local or indigenous communities.

The Indian legal system has failed to address the issue of biopiracy effectively which could have severe adverse consequences on mankind, which might even lead to extinction. Clearly there is a need for re-examining the grant of patents on life forms anywhere in the world. Meanwhile, it may be advisable to either exclude patents on all life forms or if that is not possible then exclude patents based on traditional/ indigenous knowledge and essentially derived products and processes from such knowledge. There should be insistence on the disclosure of the country of origin of the biological source and associated knowledge ,and obtain the consent of the country providing there source and knowledge, to ensure an equitable sharing of benefits.