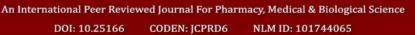
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The Role of IPR in the Protection of Biodiversity



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ABSTRACT

Biodiversity refers to the variety of living creatures found over a certain species, habitat, or region. It is also a criterion of ecological sustainability that incorporates biological variation inside and across life forms as well as inside various habitats. Intellectual Property Rights (IPR) of patents and copyrights are being enforced to emphasize the commercialization of certain inventions or products. Being well-acquainted with various research and development tools, nowadays countries are indulging in biogenetic assets. Therefore, the impact of intellectual property rights on the Biodiversity of ecosystems is required to protect them.





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INTRODUCTION:

The new technological developments, particularly biotechnology and commercial success chalked up by the pharmaceuticals and cosmetic behemoths, clearly demonstrate the significance and usefulness of traditional knowledge for the development of new product of commercial importance. Traditional knowledge associated with biological resources is the knowledge about a country's biodiversity, an intangible component of the resource itself.7 The informal knowledge about biodiversity in the traditional knowledge system is very important for sustainable use and conservation of local ecosystem and to enrich biodiversity as a whole.8 There are ample evidences of traditional knowledge and practices involved in enhancing agricultural biodiversity throughout the world. [1]

The rise in biotechnology innovation and pharmaceutical production in recent decades has resulted in the concomitant rise of IPRs (especially patents) and biodiversity prospecting.

The 1990s have been characterized by contentious debate about how to reconcile the protection of biodiversity and intellectual property rights. Two international treaties, the Convention on Biological Diversity (CBD), and the Trade Related Intellectual Property Rights (TRIPs) agreements of the World Trade Organisation (WTO) have significant implications for the nexus of intellectual property rights (IPRs), biodiversity, and associated knowledge systems. [2] [3] [4].

Before CBD came into existence, all genetic and biological resources fell into the benefit-sharing obligation in place. The most dispute circumstance in this regard has been that of the plant Rosy Periwinkle originally native to Madagascar and used in the treatment and grown in almost all of Texas to aid the manufacture of essential drugs, without any compensation to the local community or sharing of profits. CBD on the other hand identified the sovereign power a State would have over its biological resources and the need to provide a mechanism for its equitable sharing. CBD is the main international instrument that provides a comprehensive and holistic approach to the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits deriving from the use of genetic resources.^[5]

The CBD requires parties to safeguard biodiversity and the traditions and knowledge of those indigenous and other local communities associated with this biodiversity and lays down the basic elements for access to biodiversity resources and associated knowledge systems. CBD

principles most relevant to the debate over biological resources and IPRs can be summarised as (a) states have sovereign control over the biological resources within their borders and shall ensure conservation and sustainable use of their same (b) although states shall have the authority to control access to their biological resources, they shall endeavor to create conditions that facilitate such access; (c) such access shall be granted on mutually agreed terms and subject to the prior informed consent of the party providing such access; (d) the benefits of commercial or other utilization of genetic resources shall be shared fairly and equitably with the party providing such access; (e) the wider application of the knowledge, innovations, and practices of indigenous and other local communities shall be conducted with the approval and involvement of the holders of such knowledge.^[6,7]

The CBD was born at the United Nations Conference on Environment and Development in Rio de Janeiro in June 1992 (UNCED, 1992). The objectives of the CBD are threefold: first, the conservation of biological diversity; second, the sustainable use of biological diversity; and third, the fair and equitable sharing of benefits arising out of the utilization of genetic resources. The CBD embraces an ecosystem approach to biodiversity protection by defining 'biological diversity' as including "ecosystems and the ecological complexes of which they are a part", as opposed to merely an individual species approach (Article 2). The ecosystem approach recognizes the complex ecological interplay between species and acknowledges the need for a holistic approach for conservation endeavors to be truly effective (Date, 1997). The CBD also acknowledges the value and vulnerability of traditional communities and their knowledge (Article 8(j)) and requires a symbiotic flow of resource access and resultant benefits between developing and developed nations (Articles 15 and 16) whereas TRIPS is the most comprehensive international agreement on intellectual property protection to date. It contains minimum standards for international protection (Article 1), binds all GATT members, and includes effective enforcement mechanisms (Kruger, 2001; McManis, 1998). Its main objectives are the protection and enforcement of IPRs in such a way as to promote technological innovation and the transfer and dissemination of technology to the mutual advantage and socioeconomic benefit of all members (Article 7). [8].

TRIPS looks at individual rights while CBD encourages collective rights of the communities. [9].

There are three specific issues of conflict between the CBD and the TRIPs Agreement: • where patentable inventions are based on biological material, the TRIPs Agreement does not

provide for either the disclosure of the source of the material utilized in the inventions or the obtaining of prior informed consent (PIC) of the country of origin of the material; • the conventional forms of IPRs included in the TRIPs Agreement are inadequate to protect traditional knowledge effectively; and • the patenting of plant varieties. The TRIPs Agreement tends to support patents on all things and disregards PIC and disclosure of country of origin. This erodes the sovereign rights of a country over its biodiversity and encourages biopiracy, whereby a person or a corporation can transfer and own the bio-resources of a country and be associated with traditional knowledge.

The CBD recognizes community rights over biodiversity and traditional knowledge and the need for the protection of such knowledge with adequate benefit-sharing with the source communities. This is not recognized by the TRIPs Agreement, which can facilitate the wrong granting of patents and/or grant of patents based on a disregard for existing traditional knowledge in the public domain. [10]

Biological Diversity Act, 2002 of India has defined various terms: [11]

"Biological Diversity" means the variability among living organisms from all sources and the ecological complexes of which they are part and includes diversity within species or between species and of ecosystems.

Biological diversity encompasses all species of plants, animals, and micro-organisms and the variation between them, and the ecosystems of which they form a part. It occurs at three levels, namely: (i) species level - which refers to the number and kinds of living organisms; (ii) genetic level - which refers to genetic variation within a population of species; and (iii) eco-system level - refers to the variety of habitats, biological communities and ecological processes that occur in such habitats.^[12]

PROTECTION OF TRADITIONAL KNOWLEDGE ASSOCIATED WITH BIOLOGICAL RESOURCES [12]

Issues relating to protecting, recognizing, and rewarding TK associated with biological resources are very complex. The modalities for protecting TK are still emerging and evolving. The nature of entitlements and share in benefits is also a grey area. Even at the international level, clarity has as yet not emerged and countries are grappling to understand the issue.

As regards the protection of knowledge, innovations, and practices associated with biological resources, these do not seem to fall in the conventional legal systems of IPR protection (e.g., patents, copyrights, trademarks, etc.). These conventional forms of IPRs are inadequate to protect indigenous knowledge essentially because they are based on the protection of individual property rights, whereas TK is, by and large, collective. Further, the informal knowledge presents other difficulties in being recognized for IP protection, such as:

- * Knowledge is developed over some time and may either be codified in texts or retained in oral traditions over generations. The conditions of novelty and innovative steps necessary for the grant of a patent are therefore not satisfied.
- * Communities quite often hold knowledge in parallel.

Nevertheless, the development of an appropriate form of protection for the knowledge of local communities is of great interest to countries that are rich in biodiversity, and also rich in TK, such as India.

SUGGESTIONS/OPTIONS FOR PROTECTING TRADITIONAL KNOWLEDGE [12]

Various suggestions have been advanced to extend protection to knowledge, innovations, and practices. These include (i) documentation of TK; (ii) registration and innovation patent system; and (iii) development of a sui generis system.

Survey of Comparative Approaches to the IPR/Biodiversity Linkages: [13]

Some interesting initiatives are underway in the countries surveyed. Several of these initiatives -- notably those in the Andean Pact countries, the Philippines, The Gambia, and Cameroon -- were cited in a recent report by the Secretariat to the Conference of the Parties to the Convention on Biological Diversity (Biodiversity Convention Secretariat Report, 1995), and may therefore be influential in the development of other national, and perhaps multilateral, policies and legislation governing access to genetic resources.

The **Andean Pact** countries (Bolivia, Colombia, Ecuador, Peru, and Venezuela) have been working on a Common Regime for Access to Biogenetic Resources that would reflect the implement the Biodiversity Convention. The draft decision prepared to effect this common regime starts from the premise that states have sovereign rights over their natural resources, and the authority to determine questions of access to those resources. All states would declare all genetic resources to be part of the national patrimony. All-access to genetic resources, for

scientific, commercial, or industrial purposes, is to be regulated by the member-states based on prior informed consent and mutually agreed on terms. The source country is a mandatory party to any decision on access, even where the requested access is to a resource on private property. The draft decision adopts the concept of Farmers' Rights and the vesting of those rights in the international community as trustees.

The proposals leading up to the preparation of the draft decision recommended making access to genetic resources subject to governmental authorization, which would consist either of a valid Certificate of Origin (for *in situ* resources) or a Material Transfer Agreement (for *ex situ* resources). Every subsequent transfer of the accessed material would have to be accompanied by this authorization. This system would link the access requirements and intellectual property regimes: patents and other intellectual property rights would only be granted upon presentation of the Certificate as proof of prior informed consent.

Value of Biodiversity: [14]

- > Diversity is the most ecologically sustained form.
- > Diversified crops maintain soil fertility.
- > Diversity optimizes soil management in rain-fed belts.
- ➤ Diversity means insurance against crop failure.
- Diversity optimizes labor availability.
- Diversity ensures food security.
- ➤ Diversity of the range of foods ensures nutritional balance.
- Diversity provides a range of fodder to the cattle keeping them healthy and
- > Productive.
- ➤ Diversity helps women control their farm economics and seeds.

An international system of reciprocal intellectual property rights in natural and improved plant germplasm combined with economic inducements, in any of several possible forms, would benefit both developed and developing countries. Developing nations desire compensation and technology transfers in exchange for the use of their natural resources;

industrialized countries seek continued access to new, unimproved species and fiercely guard their grants of intellectual property rights in technological products and processes.^[15]

National and international regimes on access to genetic resources and the fair and equitable sharing of benefits [16]

Indirect or direct appropriation of genetic resources (or products containing genetic resources or biologically derived materials, including synthesized products), especially through patents and plant breeders' rights - PBRs, is one of the main reasons why ABS principles and rules were incorporated in the CBD as part of the great political "bargain" between developed (biologically poor) and developing countries (biologically rich). As a result, ABS regulations seek to ensure that access to biological and genetic resources is subject to certain conditions (sovereignty, mutually agreed terms, prior informed consent), which guarantee that benefits derived from the use of these resources are fairly and equitably shared among the user and the country providing them.

India is classified among the 12 mega-diversity centers of the world. India's record in agrobiodiversity is equally impressive. There are 167 crop species and 320 species of wild crop relatives and several species of domesticated animals. India is considered to be the center of origin of 50,000 varieties of rice, 1000 varieties of mango, 100 varieties of pepper, 27 breeds of cattle, 22 breeds of goat, 40 breeds of sheep, 18 breeds of poultry, 8 breeds of buffalo (the world's total biodiversity) and several other varieties of pigeon-pea, turmeric, ginger, sugarcane, gooseberries, etc and ranks seventh in terms of contribution to world agriculture. India has a rich and varied heritage of biodiversity. It has 850 species of bacteria, 6500 species of algae, 14500 species of fungi, 2000 species of lichen,2850 species of bryophytes, 1100 species of pteridophytes, 64 species of gymnosperms and 17500 species of angiosperms.

The TRIPS agreement and the international biodiversity conventions have impacted not only control over biological resources and derived products but also more generally the management of agriculture in India and other developing countries and the realization of food security and the human right to food at the individual level. [17]

NEED OF IPR FOR BIODIVERSITY [18]

Biodiversity includes all life. Since man has started exploiting the natural biodiversity for their gains and leading to the extinction of some species, endangering and threatening some

of the species that are on the verge of extinction like modified living organisms, newly found species of flora and fauna, its genetic information needs protection and preservation. That's why the concerned authority felt the necessity of Laws that can regulate, conserve, and protect biodiversity.

IPR (Intellectual Property Rights) laws encourage the commercialization of seed development, and monoculture, and protect the modified microorganisms and new plant varieties. To achieve this objective the Biological Diversity Act 2002 and the Indian Patent Act,2002 were brought to light in response to compliance with the Convention on Biological Diversity and TRIPS (Trade-Related Intellectual Property Rights).

The TRIPs agreement obliges the countries to amend their IPR regime to meet muchenhanced International standards which can protect Biodiversity and associated knowledge systems.

The objective of the CBD is to encourage the conservation, preservation, and sustainability of the components of biological diversity. According to the preamble, the TRIPS Agreement is designed to "promote effective and adequate protection of intellectual property rights". Both conventions ensure the sustainability of biological diversity and conserve it for future use. These rights are safeguarded by the National Biological Authority of India.

In recognizing the importance of Intellectual Property Rights, the Biological Diversity Act, of 2002 has a special mention for the application of provisions of the Act to Intellectual Property Rights in Section 6.

This section clearly states that "No application for Intellectual Property Rights can be filed in any country without prior NBA (National Biodiversity Authority) approval." The first provision of the act states that in the event an application is filed, NBA permission may be obtained after the acceptance of the patent, but before the patent grant by the patent authority concerned.

It is quite clear from Section 2(c) of the Biological Diversity Act, 2002 that the legislation mainly directs toward patenting of biological inventions, which puts an additional burden, largely regulatory, on the applicant to comply with.

Under recent Indian Patent Office practice, it can be seen that for patent applications that contain any biological material, in the First Examination Report, it is almost casual to come across an objection requiring clarification as to furnish NBA approval in case of the use of any biological resource obtained from India. So, it can be observed from Section 6 of NBA that the grant of the patent would be kept in abeyance until proof of NBA approval is provided. For example, the use of biological resources for validation purposes of a claimed product would fall under the ambit of the NBA.^[19]

Patents and other forms of intellectual property then take their place and role in delivering a part of the compensation (and incentive) contributing to the marginal private return. [4] This is achieved, at least in theory, by capturing some of the value from innovative, creative, and useful applications of the accessed biological resources and returning this as part of the price paid for access and use of the biological resources through the royalty or other benefits (such as access to and transfer of new technology, and so on). [20]

Some of the patentable inventions 1. Genetically modified microorganisms 2. Nucleotide sequences and Amino acid sequences 3. Methods of extraction of bioactive compounds from plant or animal kingdoms. 4. Methods of making disease-resistant, drought-resistant plant varieties 5. Processes of making genetically modified plants with desirable characteristics. 6. Herbal extracts and methods of obtaining them 7. Cultures and methods of culturing and Nutrition mediums etc.^[21]

Minimum requirements of a sui generis system for the protection of plant varieties

WTO member states that exclude plant varieties or even plants in general from patentability have to provide for the protection of plant varieties by an "effective *sui generis* system." Although the TRIPS Agreement does not give any details on what elements this effective *sui generis* system would have to include, certain minimum requirements that such a system would have to fulfill may be drawn from the context of Article 27.3(b), the context of the agreement as an integral part of the WTO Agreement, and finally from the objectives of the TRIPS Agreement itself. Five such requirements can be discerned:

□ the *sui generis* system has to be an intellectual property right, i.e. a legally enforceable right, either to exclude others from certain acts of commercial relevance about the protected plant variety or to obtain remuneration in respect of at least certain uses of the plant variety by third parties.

| ☐ Since the TRIPS Agreement elaborates no further upon the term "plant variety" and does |
|---|
| not specify any species or genera, member states might have to provide for the protection of |
| plant varieties, whatever species or genus they belong to. |
| |
| ☐ The sui generis system needs to comply with the basic principle of "national treatment." |
| This means that member states have to treat the nationals of other members no less favorably |
| than their nationals about the protection of plant varieties. |
| |
| ☐ Any advantage, favor, privilege, or immunity granted by a member to the nationals of any |
| other country has to be accorded immediately and unconditionally to the nationals of all the |
| other member states ("most-favored-nation treatment"). |
| |
| ☐ Finally, to be effective, a <i>sui generis</i> system requires an enforcement procedure to permit |
| action against any act of infringement of the sui generis right. |
| The TRIPS Agreement only sets minimum standards; thus member states are free to provide |
| for additional IPR or any other rights, such as Farmers' Rights, Indigenous Rights, etc., which |
| are not covered by the agreement, as long as they do not conflict with any obligations the |
| agreement poses about other IPRs. However, IPR systems may well not be the most effective |
| agreement poses about other if its. However, if it systems may well not be the most effective |

IPRs vs. Biodiversity [23]

mechanism to protect such other rights. [22]

The CBD has two interesting provisions relating to IPRs. Article 16.5 states that Contracting Parties shall cooperate to ensure that IPRs are "supportive of and do not run counter to the CBD's objectives." However, this is "subject to national legislation and international law." Article 22 states that the CBD's provisions will not affect the rights and obligations of countries under "existing international agreements, except where the exercise of those rights and obligations would cause serious damage or threat to biological diversity." Read together and in the spirit of the CBD, many people have concluded there is a basis for countering the seemingly inexorable march of the IPR regimes described above. But for this argument to hold, the actual impacts of IPRs on biodiversity need to be examined. This is a difficult subject, for many impacts are hard to assess. However, the following must be considered [18]:

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➤ Current IPR regimes have allowed industrial and commercial interests to appropriate the resources and knowledge of resource-rich but economically poor countries and communities, further impoverishing them and denying them the benefits of technological innovation;

- ➤ IPRs are likely to greatly intensify the trend of homogenization of agricultural production and medicinal plant use systems. In agriculture, for instance, any corporation that has spent enormous amounts of money obtaining an IPR would want to market its varieties in as large an area as possible. The result could be serious displacement of local diversity of crops (though of course, IPRs would not be the only factor);
- ➤ Increasingly, species-wide IPRs (such as those for transgenic cotton and soybeans) could stifle even public sector and small-scale private sector crop variety development;
- ➤ Having to pay substantial royalties to industrial countries and corporations could greatly increase the debt burdens of many countries. This could further intensify the environmental and social disruption that is often caused when debt repayment measures are taken up, such as the export of natural products;
- Farmers who innovate on seeds through re-use, exchange with other farmers, and other means, would be increasingly discouraged from doing so if the tighter regimes that UPOV 1991 sanctions are imposed on their countries; these regimes would also increase the economic burden on farmers, further discouraging innovation;
- ➤ The ethical aspects of IPRs are serious and to many communities and people the most important reasons for opposing current IPR regimes. The patenting of life forms is abhorrent to many traditional societies and modern conservationists because of the underlying assumption that nature exists apart from, and solely for the use of, humans. The privatization of knowledge is also repugnant to many societies that hold the knowledge to be largely, though by no means solely, in the public domain.

The implications of providing physical access and IPR protection to foreign consumers of biodiversity on the biodiversity conservation provided using an integrated model of optimal resource extinction and shared resource harvesting game is presented. The model results show that, as foreign and indigenous users compete for the same open-access resource, optimal extinction may occur as a noncooperative equilibrium under certain bioeconomic conditions. Extinction may be prevented by forging successful cooperation between consumers and initiating a joint harvesting process. Depending upon the model parameters, even under cooperation, increased patent protection and physical access either promote the conservation of biodiversity or enhance its physical exploitation. [24,25]

CONCLUSION:

Biodiversity is a vital component of ecology that is inextricably related to individual existence. IPR is the most important aspect that offers acknowledgment and privileges for advancement. It is well understood how the utilization of environmental assets is extremely useful to humans. Hence, IPR protects biodiversity around the world and preserves or encourages the long—term use of genetic variation to assure its survival for upcoming generations. Also, to maintain a reasonable and balanced sharing of income derived from genetic and biological resources.

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