REGULATION OF BIO-PROSPECTING AND RELATED INTELLECTUAL PROPERTY RIGHTS IN INDIA

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Abstract

Biological resources and related traditional knowledge are known for possessing great commercial value. They are being utilized by large organizations and corporations to their personal commercial interests by obtaining exclusive access to bio resources. This exploitation by corporate giants has led to the denial of benefits to the rightful holders of such knowledge and resources. This brings to the forefront the terms like ‘bio-prospect’, ‘bio-research’ and ‘bio-utilization’ and raises questions regarding their regulation.

The utilization of existing knowledge takes place within the broad framework of public law i.e. international and national conventions governing protection of biological diversity, and private law, within the realm of bio prospecting contracts worldwide. This research paper thus aims to analyze bio prospecting and its limits within the permissible contours of law. It purports to study the regulation governing bio-prospecting and the strengths and weaknesses of such regulation. It also discusses unauthorized bio-prospecting in the form of bio-piracy, dealing with specific case of genetically modified crops introduced in Indian market by Monsanto. It also aims to resolve and provide suggestions to overcome the lacunae in regulation.

SECTION 1 REGULATION OF BIO-PROSPECTING

This section deals with the concept of bio-prospecting and bio-piracy. Further, it identifies the strengths and weakness in the regulation of bio-prospecting under the Indian and international framework.

1. UNDERSTANDING BIO-PROSPECTING

Traditional knowledge, in its simplest form, has been defined as knowledge developed over a long period of time, which has been passed down from one generation to another generation.\(^2\)

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1 Vth year, NLIU Bhopal

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The Convention of Biological Diversity defines traditional knowledge as knowledge, innovations, and practices of indigenous and local communities embodying traditional lifestyles.\(^3\)

Traditional knowledge, an intangible form of knowledge, has been a source for useful research. Such research has not only proved worthy for basic human survival through traditional remedies, but has also reassured human life through its use in life saving drugs and medicines. Traditional knowledge has the potential of providing commercial benefits by development into useful products and processes. The scope for such productive research and commercially beneficial results has given rise to the concept of bio-prospecting.

Bio-prospecting literally means search for bio resources and/or traditional knowledge. In an ASEAN Workshop on TRIPS Agreement, it has been defined as the systematic search for and development of new sources of chemical compounds, genes, micro-organisms, macro-organisms, and other valuable products from nature.\(^4\) It was further said that bio-prospecting entails the search for economically valuable genetic and biochemical resources from nature.\(^5\) In other words, it is the search for biodiversity related substances, having the potential of being developed into marketable commodities such as pharmaceuticals, pesticides and cosmetics.\(^6\) Furthermore, bio-prospecting is inclusive of both (1) search for novel indigenous forms of knowledge by commercial actors, and (2) search for previously unknown compounds in organisms that have never been used in traditional medicine.\(^7\)

Let us deal with two cases of bio-prospecting (in and outside India) to understand situations where it could be a boon or bane to the society. The most successful and often quoted case of bio-prospecting deals with the Kani tribe of the Western Ghats. The Kani tribe was known for a


\(^3\) Article 8(j), Convention on Biological Diversity 1760 UNTS 79 (June 5, 1992) [hereinafter ‘CBD’].


\(^5\) Supra note 4.

\(^6\) Michael Davis, *Biological Diversity and Indigenous Knowledge*, 4 RESEARCH PAPER NO 17, AUSTRALIAN PARLIAMENTARY LIBRARY (1997-8).

\(^7\) S. Kannaiyan, *Biological Diversity And Traditional Knowledge*, NATIONAL CONSULTATION WORKSHOP ON AGRO BIODIVERSITY HOTSPOTS AND ACCESS AND BENEFIT SHARING (July 19-20, 2007); *INTRODUCTION TO BIOTECHNOLOGY, GLOSSARY* (Pearson Education India, 2009).
substance *arogyapacha*, which would help build stamina and reduce fatigue for men travelling long distances. Apprising themselves of this traditional knowledge, scientists from Tropical Botanical Garden and Research Institute entered into benefit sharing arrangements with the Kani tribals of Kerala and developed a drug called Jeevani. This body energizing drug, Jeevani, was then licensed to the Arya Vaidya Pharmacy Ltd., an Indian pharmaceutical manufacturer pursuing the commercialization of Ayurvedic herbal formulations. Honouring the benefit sharing agreement, a Trust Fund was also established to share benefits from the commercialization of the drug.

Another example of bio-prospecting involves the case of rosy periwinkle of the island of Madagascar. This plant produced alkaloids that helped in cure of most victims of the Hodgkin's disease and acute lymphocytic leukemia. This was used by Eli Lilly to produce two life saving anti-cancer drugs, Vincristine and Vinblastine. In the absence of an adequate regulatory mechanism, although the company utilized the traditional knowledge and befitted from sale of drugs, but it neither entered into or honoured any benefit sharing agreement, nor did it share royalties arising from it with the Malagasy people.

2. LEGAL ISSUES WITH BIO-PROSPECTING

The legal issues related to bio-prospecting vis-à-vis protection and preservation of traditional knowledge at the international level has been brought to the fore front at the instance of certain developing nations. These nations, being inherently rich in biological resources and traditional knowledge, have become the epicenter of research and exploitation by the developed nations. The need for a comprehensive legislation, fully equipped with countering all forms of exploitation, has been reiterated by developing nations.

It has been observed from the past two decades, that private corporations from all over the world have pressed for acquisition of intellectual property rights over their research on biological

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10 Ibid.
resources and traditional knowledge as a way of maximizing their income generation. Claims of patent as a form of IPR have become a common way of establishing monopoly over these resources/knowledge. The grant of patent by the U.S. Patent Trade Office on *Neem*\(^{12}\), *Turmeric*\(^{13}\) and *Conospermum*\(^{14}\) are examples of IPRs over traditional knowledge possessed by India. Other examples which have impacted the world are the US plant patent on the ayahuasca plant, considered sacred and used for medicinal purposes by Amazon's indigenous peoples; the patent of crop varieties of Basmati rice by Rice-Tec Corporation in the US; the patenting of human genetic material i.e. human cell line of a Hagahai tribesman from Papua New Guinea in the US etcetera.\(^{15}\)

The broad legal issues regarding bio-prospecting that have arisen are as follows:

- Research of pharmaceutical companies basing on traditional knowledge developed by the indigenous communities,
- Unauthorized access to biological resources or traditional knowledge (claims of biopiracy),
- Patenting the research or innovations of traditional communities,
- Other claims of intellectual property rights based on traditional knowledge/biological resources, and
- Inadequate sharing of benefits with the holders of traditional knowledge.

The unauthorized access to biological resources and traditional knowledge has often given rise to claims of bio-piracy, which has been explained in the following part.

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\(^{11}\) S. Kannaiyan, *Biological Diversity And Traditional Knowledge*, NATIONAL CONSULTATION WORKSHOP ON AGRO BIODIVERSITY HOTSPOTS AND ACCESS AND BENEFIT SHARING (July 19-20, 2007).

\(^{12}\) US Patent (No. 5,124,349).

\(^{13}\) US Patent (No. 5,401,504).

\(^{14}\) US Patent (No. 5672607).

3. UNDERSTANDING BIO-PIRACY

The Oxford Dictionary defines Biopiracy as: “the practice of commercially exploiting naturally occurring biochemical or genetic material, especially by obtaining patents that restrict its future use, while failing to pay fair compensation to the community from which it originates”.[16]

The ETC Group, which originally coined the term, gives the following definition: “Biopiracy refers to the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions that seek exclusive monopoly control (patents or intellectual property) over these resources and knowledge.”[17]

The Indian scientist Vandana Shiva gives the following definition: Biopiracy refers to the use of intellectual property systems to legitimize the exclusive ownership and control over biological resources and biological products and processes that have been used over centuries in non-industrialized cultures.[18]

The term biopiracy gathered attention when the third world nations realized the exploitation of their biological resources at the hands of the developed nations under the guise of research and development of these resources.[19] The term denotes unauthorized commercial use without compensation to third world countries where the resources are found.

Bio-piracy may be practiced in the following ways: (1) access and use of biological resource or traditional knowledge without the authorization of the country of origin and indigenous communities that hold and develop these resources; or (2) absence of benefit sharing with the communities who are the rightful owners of these resources.[20]

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Bio piracy causes interference with the sovereignty of a nation since the individuals and corporations belonging to other jurisdictions obtain patents on biological resources originating in other countries. Thus bio-piracy not only violates the concept of common heritage of mankind, but also violates a nation’s sovereign rights to its own resource.

4. INTERNATIONAL LAW REGULATING BIO-PROSPECTING

While we have delved into the legal issues concerning bio-prospecting, especially the case for bio-piracy, it involves the need to have appropriate policies and institutions to ensure authorized access to biological resources.\(^1\) Irrespective of the form, the legality of such agreements depends on whether or not they confirm to broad international law principles regarding protection of traditional knowledge and biological diversity.

4.1 Convention on Biological Diversity, 1992\(^2\)

4.1.1 State sovereignty

The CBD is based on the principle of recognition of the sovereign rights of states over genetic resources. This right has been provided due to the difference in *in-situ* conditions in territories of States. This makes CBD a one of its kind convention which requires parties to uphold within their jurisdictions, the rights of other parties to the CBD over their genetic resources. This is furthered by the rights provided under Article 15. Bio-prospecting contracts are primarily based on the three objectives as laid down in the Article 15, namely that of disclosure of source of country of origin of the biological resource, prior informed consent & fair and equitable sharing of benefits.

This indicates that the access to genetic resources required for bio-prospecting shall be subject to the prior informed consent of the party providing such resources and a fair and equitable sharing

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\(^1\) W.V. Reid et al., *Biodiversity Prospecting: Using Genetic Resources for Sustainable Development* 1 (World Resources Institute 1993).

\(^2\) CBD, *Supra* note 3.
with that party of the benefits that arise from the commercial and other utilization of those resources (indigenous people).\textsuperscript{23}

\textbf{4.1.2 Protection of innovations of local communities}

Article 8(j) of CBD provides for preservation and maintenance of knowledge, innovations and practices of indigenous and local communities. Article 10(c) further provides that each party shall protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements.

These articles protect the rights of local communities to their innovation and customary use of bio-resources. The authorization to bio-prospect must therefore be given subject to these rights of indigenous people.

\textbf{4.2 Rio Earth Summit}\textsuperscript{24}

The Statement of Forest Principles, one of the outcomes of the Rio Earth Summit recognizes the entitlement of indigenous peoples to an equitable sharing of any benefits arising from the utilisation of their traditional knowledge of those environments.\textsuperscript{25}

\textbf{4.3 Declaration on the Rights of Indigenous Peoples}\textsuperscript{26}

Article 24 of the declaration provides for Indigenous peoples’ rights to their traditional medicines and health practices, including the right to the protection of vital medicinal plants, animals and minerals. Article 29 provides that Indigenous peoples are entitled to the recognition of the full ownership, control and protection of their cultural and intellectual property. The Article states that peoples:

\textsuperscript{23} Kabir Sanjay Bavikatte and Morten Walløe Tvedt, \textit{Beyond The Thumbrule Approach: Regulatory Innovations For Bioprospecting In India 11/1 LAW, I ENVIRONMENT AND DEVELOPMENT JOURNAL} (2015) [hereinafter ‘Beyond the Thumbrule Approach’].


\textsuperscript{25} Principles 5(a) & 12(d), Forest Principles, Rio de Janeiro (1992).

\textsuperscript{26} UN General Assembly, \textit{United Nations Declaration on the Rights of Indigenous Peoples}, A/RES/61/295 (October 02, 2007).6

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have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs and visual and performing arts.

4.4 Nagoya Protocol

It mandates the parties to ensure that users of biological resources and related traditional knowledge (bio-prospectors) existing within their jurisdiction to adhere to the benefit sharing regulatory pre-requisites of the source countries. The bio-prospectors are required to comply with the following:

- the access and benefit sharing regulatory pre-requisites of the source countries, and
- the utilization of above mentioned resources on the basis of mutually agreed terms between the bio-prospectors and the source country.

5. INDIAN LAW REGULATING BIO-PROSPECTING

The Contracting Parties, recognizing the influence of patents and other intellectual property rights on implementation of CBD, Article 16(5) provides that States shall cooperate subject to national legislation and international law to ensure that such rights are supportive of and do not run counter the objectives of CBD.

India has been held to be a significant source country for bio-prospecting. This is evinced by the fact that 80 percent of the medicinal plant patents in the U.S. are of Indian origin, and 50 percent of the drugs reported in the British Pharmacopoeia have their origins in medicinal plants from the Western Himalayas. With such concerns rising in India, the Biological Diversity Act,

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27 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity (12 October, 2014).
30 JUBILEE PURKAYASTHA, EMERGING TRENDS IN SUSTAINABLE BIOPROSPECTING OF BIORESOURCES 13 (Springer, Aug 16 2016).

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2002\(^{31}\) and the Biological Diversity Rules, 2004\(^{32}\) were passed by the legislature to regulate bio-prospecting of Indian biological resources and associated traditional knowledge.

Though there is no statutory definition or use of the term bio-prospecting in the BDA and the BD Rules, it can be read into the definition of ‘bio-survey’ and ‘bio-utilisation’ given under Section 2(d) of BDA. The framework for regulation of bio-prospecting through necessary approvals and safeguards has been analysed below:

5.1 **Prior approval from the National Biodiversity Authority**

In consonance with its international obligation, the BDA provides for a mechanism of prior approval from the National Biodiversity Authority set up under Section 8 of the Act, for the following activities:

- Application for intellectual property rights for any invention based on any research or information on a biological resource obtained from India.
- Obtaining any biological resource occurring in India or associated knowledge for research or commercial utilization or bio-survey and bio-utilization or transfer of results.\(^{33}\) This applies as an additional protection to non-citizens, non-residents and body corporation/association not registered in India.\(^{34}\)
- Transfer of biological resource or knowledge.\(^{35}\)

While granting such approvals under section 19 or section 20 for the above mentioned activities the authority must ensure that the terms and conditions for grant of approval secures equitable sharing of benefits arising from use and access of the biological resources.\(^{36}\)

5.2 **Prior Intimation to the State Biodiversity Board**

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\(^{31}\) Hereinafter ‘BDA’.
\(^{32}\) Hereinafter ‘BD Rules’.
\(^{33}\) BDA, *Supra* note 31, Section 19(1).
\(^{34}\) BDA, *Supra* note 31, Section 3.
\(^{35}\) BDA, *Supra* note 31, Section 20(2).
\(^{36}\) BDA, *Supra* note 31, Section 21(1).
Additional safeguards are mentioned in BDA in the form of prior intimation to the State Biodiversity Board. Any citizen of India or a body corporate registered in India shall provide prior information to the State Biodiversity Board for undertaking activities such as obtaining any biological resource for commercial utilization, or bio-survey and bio-utilization for commercial utilization.37

6. CRITICAL ANALYSIS OF BIO-PROSPECTING REGIME IN INDIA

6.1 Strengths in regulation of bio-prospecting

- The BDA covers within its ambit of approval a number of facets such as research in biological resources, bio-survey or bio-utilization which means survey or collection of biological resources for any purpose and commercial utilization of these by pharmaceutical drug companies. Thus for all activities involved in the process of bio-prospecting are under the strict scrutiny of the National/State authorities.

- Further, Rule 14 of the BD Rules requires the approval by the National Biodiversity Authority to be in the form of a contract between the authority and the bio-prospector. Section 3 of the BDA read with Rule 14 of the BD Rules therefore allows for the NBA to enter into scoping agreements with bio-prospectors.38 These agreements can be used to provide speedy approvals for bio-prospecting and can include specific restrictions as to what will not be allowed during the scoping phase of bio-prospecting. Therefore bio-prospecting is to be conducted within the four corners of the bio-prospecting contract. These provisions also ensure effective, efficient and transparent access procedures through written agreements and applications in prescribed formats. Rule 14(6) of the BD Rules provides for the agreement to mention the intended use of research on biological resources and its commercial utilization.

- The BDA under Section 24 also provides for confidentiality of information (not to be disclosed in any case) received by National/State authorities to decide on granting approval. Such non-disclosure makes it in consonance with intellectual property laws. This secures the claim of patent for a person/organization as the information does not come under public domain.

37 BDA, Supra note 31Section 7.

38 Beyond the Thumbrule Approach, Supra note 23, at 20.
New Invention under Section 2(1)(l), Patents Act 1970 considers prior art to be anything not anticipated by publication or use in India or elsewhere in the world before the date of filing. Thus if anticipation could have occurred anywhere in the world, such a claim cannot be patented. Under the US Patent Act, before the 2014 amendment, the definition of novelty mentioned that a patent could not be granted if someone in the United States knew the invention, or used the invention, or in any other country patented the invention, or described the invention in a printed publication. This meant that an act of biopiracy of an Indian traditional knowledge could be challenged by India only if some written proof of that knowledge could be produced, for want of which such biopiracy would continue. However, the US patent law underwent an amendment in 2014, and has now removed the distinction between public use in India or elsewhere. It now states that an invention is unpatentable if it was patented or described in a printed publication, or in public use, or on sale, or is otherwise available to the public.\(^{39}\) Therefore, public use of an invention by someone besides the inventor in any country (not just the U.S.) will be considered prior art under the new U.S. law. This has proved to be one of the positives in the regulation of bio-prospecting, making the challenge of biopiracy claims by India simpler and in consonance with both definitions.

### 6.2 Weaknesses in regulation of bio-prospecting

- One of the weaknesses of BDA is the involvement of only one stakeholder in the approval mechanism i.e. the National/State authority. The regulation of access, utilization or transfer of results is done by NBA and SBB and not the local communities. Even Rule 14(3) requires only consultation with local communities, keeping them away from the decision making process. As a consequence, State would be inclined to grant approvals to the bio-prospectors which will further State’s economic interests.

- The BDA does not provide power to citizens to directly approach the courts in case of either violation of the provisions of BDA/BD Rules or any alleged claim of violation of intellectual property rights. Such power is restricted to an appeal in the High Court against any order by the National Biodiversity Board or the State Biodiversity Board.\(^{40}\)

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\(^{39}\) 35 U.S. Code § 102 - Conditions for patentability; novelty.

\(^{40}\) BDA, *Supra* note Ошибка! Закладка не определена., Section 52.
State has an obligation to protect indigenous knowledge and innovations of local communities under various international conventions and protocols. However, the BDA merely requires the Central Government to endeavor to respect and protect such knowledge, rather than defining in clear legal language the terms of such protection. Consequently, the pharmaceutical bio-prospectors ultimately rely on the knowledge of traditional communities and obtain intellectual property rights on the same.

SECTION 2 MONSANTO: A CASE STUDY OF BIOPIRACY

This section of the paper deals with a case study of Monsanto Corporation, a U.S. biotech firm, alleged of unauthorized bio-prospecting, consequently indulging in biopiracy. It discusses the introduction of Bt brinjal in India in the backdrop of the controversy surrounding genetically modified (GM) crops in India.

7. A BRIEF BACKGROUND


The Genetic Engineering Approval Committee41 (GEAC) approved field trials of Bt Brinjal in 2007 and in February 2008, Supreme Court lifted the ban it had imposed earlier on the field trials of GM crops this stirred the debate over Bt Brinjal and yielding to the public outcry, the government imposed a temporary moratorium.

In 2011, an NGO filed complaint against MMB targeting the tripartite agreement among Maharashtra Hybrid seeds Company Pvt. Ltd., (Mahyco), University of Agricultural Sciences, Dharwad, (UAS) and Sathguru Management Consultants Pvt. Ltd., the national coordinator for the Agricultural Biotechnology Support Project (ABSP) – II project, which is led by Cornell and funded by the United States Agency for International Development (USAID).

41 An ad hoc 30-member committee comprising mainly bureaucrats and scientists.
During feeding trials, Bt brinjal showed significant differences compared to the best corresponding non-Bt controls: Bt brinjal appears to contain 15% less kcal/100 gm, has a different alkaloid content, and 16-17 mg/kg Bt insecticide toxin poorly characterized for side effects, and produced by the plant genetically modified for this.\textsuperscript{42} Rats which consumed it had diarrhoea, higher water consumption, liver weight decrease as well as relative liver to body weight ratio decrease. All these results further added fuel to the fire.

8. ALLEGATIONS REGARDING VIOLATION OF THE BIOLOGICAL DIVERSITY ACT, 2002

The initiation of legal proceedings against Monsanto and its Indian collaborators started with filing of complaint to Karnataka Biodiversity Board (KBB) in February 2010 by Environmental Support Group (ESG), an NGO based in Bangalore.

8.1 Grounds of Allegations by ESG:

i. ESG’s complaint said that Monsanto and its collaborators accessed at least 10 brinjal varieties from Karnataka and Tamil Nadu without seeking prior consent of the National Biodiversity Authority (NBA) and State Biodiversity Boards,\textsuperscript{43} thereby violating sections 3 and 7 of the BDA.

ii. Section 41(2) requires the permission of not only the NBA and the State Board but also local biodiversity authorities and since such permission was not taken, the local communities who developed the biological resources were deprived of their right to benefit from the commercial gains.

iii. Also post formulation and issuance of guidelines by the Central Government on 08 November, 2006 the three parties failed to approach the NBA, under section 18, for approval and clarification of such guidelines.

8.2 Reply Given By Monsanto and its collaborators:-

\textsuperscript{42} Pr. Gilles-Eric Seralini, \textit{Effects On Health And Environment Of Transgenic (Or Gm) Bt Brinjal}, UNIVERSITY OF CAEN (France, January 2009).

\textsuperscript{43} http://www.downtoearth.org.in/coverage/whose-germplasm-is-it-39206.

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i. Monsanto sought protection under Section 5 of BDA, which provided that any collaborative research between Indian and foreign parties approved by the Central Government that conform to the guidelines need not seek prior approval from NBA under Section 3 of BDA.

ii. Mahyco argued that it does not share any royalty fee when transferring the technology of developing bt brinjal from local variety to UAS-Dharwad. Mahyco added that the sublicense agreement did not stipulate any commercial use of gene technology.

iii. UAS-Dharwad claimed that ABSP-II project was initiated with and approved by the Department of Biotechnology, the Ministry of Science and Technology of the Government of India. With such credible approvals obtained from various competent authorities, Monsanto tried to justify its claim.

The complaint was thereafter forwarded to the NBA, which after perusal of the complaint, concluded that the said research project prima facie fell out of the purview of the issued guidelines. Therefore, Monsanto and its collaborators cannot seek exemption under Section 5(1) of BDA, and should have obtained NBA’s prior approval.

9. WHETHER THE MONSANTO DECISION IS JUSTIFIED UNDER THE FRAMEWORK OF BDA?

The allegation relating to the violation of the guidelines issued by Central Government under section 5(3)(a) of BDA appears to lack strength since the collaboration agreement under dispute was entered into with consent of the Department of Biotechnology. Thus the conditions of the BDA were fulfilled and there was no violation.

The argument regarding violation of section 7 about non-intimation to the Karnataka State Biodiversity Board has no merits because intimation herein is required only in cases pertaining to commercial utilization and the present tripartite agreement under dispute does not state that it has

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44 Notification S.O. 1911 (E) (08 November, 2006).
commercial goals. In fact, the agreement seems to aim at technology transfer by Monsanto to its Indian collaborators and not commercial utilization.\(^{47}\) For a better analysis the following factors must be considered:

A. The Preamble to the agreement states that it focuses “on the safe and effective development and commercialization of bio-engineered products in developing countries."\(^{48}\)

B. The agreement entered into between Mahyco & Sathguru aimed at research and development of pest resistant varieties of brinjal.\(^{49}\) Therefore it is clear that the parties were attempting to circumvent the law by usage of terms like research and development instead of commercial utilization. These reasons require an in-depth investigation of the matter.

The allegation on the violation of section 41(2) of BDA is quite weak, since the provision requires the NBA and the State Boards, and not the applicant, to consult with local biodiversity management committees. Therefore only the NBA can violate section 41(2) and not UAS, Mahyco or Sathguru.

Therefore the Bt brinjal case exposed a weak regulatory system of access to biological resources in India and requires substantial amendment to strengthen existing regulation.

10. SUGGESTIONS & CONCLUSIONS

10.1 Greater stakeholders/More representation

It is suggested that the NBA may consult and negotiate with the communities and indigenous people to grant approval and even work out benefit sharing mechanisms after the decision to allow access is made. This would lead to a more inclusive stakeholder approach, taking into consideration the claims of bio-piracy and other property rights at an early stage. There must also be greater representation of local communities, by having provisions in the BDA, giving them some position in the National/State Boards.


\(^{48}\) Sublicense Agreement between MHYCO, Sathguru Management Consultants & University of Agricultural Sciences (02 April, 2005).

\(^{49}\) *Ibid.*
10.2 Complaints/Suits

There must be provisions in the BDA empowering citizens to file suits to the High Court in case of a claim for violation of bio-piracy, any unauthorized use of biological resources, unauthorized use of innovations of indigenous people and violation of provisions of the BDA/BD rules. Thus, the unauthorized use can be prevented through a suit for injunction rather than only an appeal to the High Court post the unauthorized use.

10.3 Better Enforcement

The NBA requires a contract to be entered into between the bio-prospector and itself under Rule 14(5) of the BD Rules. However signing of the contract is not the final stage to any bio-prospecting agreement, whereas monitoring is the quintessential ingredient to a successful contract. Supervision is required for sample collection, evaluation of collection method, sampling quantity to avoid overharvesting, environmental impact assessment, and most importantly for associated benefit sharing. It is suggested that this also be undertaken by the National Biodiversity Authority in terms of post contractual enforcement.

10.4 Uniformity in regions

A suggestion can be taken from the regional agreement known as the Andean Pact Common Regime on Access to Genetic Resources. This agreement was entered into between Bolivia, Colombia, Ecuador, Peru and Venezuela in 1996 and successfully agreed to a common legal regime for granting access agreements for bio-prospecting. The common regime would require government of each State to conform to the bilaterally negotiated general rules. This was done to avoid unnecessary competition between rich biodiverse countries, sharing similar geographical region, which are a potential market for lesser resourceful countries. This will prove to be a positive step for the Indian government if such an agreement could be entered between India and major biologically diverse countries.

50 Pooja Bhatia & Archana Chugh, Role of marine bioprospecting contracts in developing access and benefit sharing mechanism for marine traditional knowledge holders in the pharmaceutical industry, GLOBAL ECOLOGY AND CONSERVATION 3 176–187 (January 2015).

51 Andrew W. Torrance, Bioprospecting and The Convention on Biological Diversity, HARVARD LAW SCHOOL (accessed at https://dash.harvard.edu/bitstream/handle/1/8965586/Torrance__Andrew_00.html?sequence=2).

52 Supra note 51.
To conclude, the existing framework consisting of BDA and BD Rules for dealing with bio-prospecting contracts is adequate for regulating authorized as well as unauthorized use of bio-resources. The provisions concerning prior approval from NBA and State Boards for bio-prospecting in India help such authorities to take cognizance of the matter. Further, requirement of specific approval from NBA under section 6 of BDA before making an application for an intellectual property right is an added safeguard. Nonetheless, section 5 provides an exemption for approval in case of transfer or exchange of knowledge in a collaborative research project between an Indian and foreign bio-prospector. This means that a claim for bio-piracy in case of commercial utilization would be rejected on literal interpretation of section 5 when it involves a government entity. Therefore section 5 leads to the defeat of genuine claims of bio piracy and thus requires considerate redrafting by the legislature.