Balancing Innovation and Ethics in Bioprospecting: Navigating Intellectual Property Rights Challenges

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ABSTRACT

Bioprospecting refers to the systemic search of biochemical or genetic compounds occurring freely in nature or that which can be synthesized for the purpose of commercial exploitation However this intellectual process like most of its kind is not bereft of its issues, mostly centering around the realm of IPR. This paper will focus on the ethical concerns surrounding IPR in the sphere of bioprospecting which covers within its ambit but is not limited to patenting of conventional knowledge, benefit-sharing, and access to genetic resources amongst others. The present paper shall also shed light on the non-harmonious relationship between IPR protection and Native people's rights and seek to impress the need for ethics in the field. This research also illustrates the need for an IPR regime that respects conventional knowledge systems and ensures equitable distribution of benefits from natural resources while at the same time promoting ecological sustainability. By examining the intersection of IPR, bioprospecting, and ethics, this study contributes towards developing a more inclusive and socially responsible regimen of bioprospecting.

Keywords: Bioprospecting, IPR, Benefit Sharing, Biopiracy

INTRODUCTION

Bioprospecting is defined as the exploration of natural resources aimed at identifying compounds of genetic or biochemical value that may be commercially exploited, particularly in regions characterized by high biodiversity. This methodology possesses considerable promise for stimulating innovation, especially in the fields of pharmaceuticals, agriculture, and biotechnology. However, the commercial use of these resources often involves complex ethical and legal issues, especially regarding traditional know-how and the rights of native

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communities.[3] IPR plays a crucial role in bioprospecting as it legally protects innovations from original or sourced natural resources. Patents and trademarks are branches of IPR, which encourages innovation through the exclusivity of rights to inventors in order for them to have an opportunity to regain invested money and time. However, the application of IPR in bioprospecting raises several ethical concerns, especially when traditional or age-old knowledge is subjected to appropriation without adequate compensation or acknowledgment.[4]

Bioprospecting is not a new expression; it emanates from colonial explorations whereby the natural resources of the colonized territories were usually exploited to the benefit of the colonizers. In the modern world, bioprospecting occurs in a more formalized manner, often as scientific research and development, but with powerful commercial interests. The current scenery in bioprospecting, in contrast, is one of growing awareness of the need to balance commercial interests against those of rights of the native populace and biodiversity conservation.[5]

THE ROLE OF BIOPROSPECTING IN INNOVATION AND COMMERCIAL EXPLOITATION

Bioprospecting plays a magnanimous part in the creation of life-changing technologies, especially in the form of new pharmaceuticals, agricultural products, and industrial enzymes. For example, the discovery of *taxol* from the Yew tree of the Pacific and *artemisinin* from sweet wormwood has revolutionized cancer and malaria therapies, respectively. However, these examples also highlight the ethical concerns surrounding bioprospecting particularly wrt ownership and management of genetic resources and native knowledge. The main stakeholders in bioprospecting include native communities, who often have ancient know-how related to the use of innate resources; while the corporations on the other hand wish to utilize those resources for commercial gain while the governments seek to control access to the genetic resources.

[3] ETC Staff, Bioprospecting/Biopiracy and Native Peoples, ETC Group, *Available at* https://www.etcgroup.org/content/bioprospectingbiopiracy-and-native-peoples (Accessed 5th Sept, 2024).
[4] Baby T, B., & Narasimman Kuppusami Suriyaprakash, T., Intellectual Property Rights: Bioprospecting, Biopiracy and Protection of Conventional knowledge - An Indian Perspective IntechOpen, A*vailable at:* http://dx.doi.org/10.5772/intechopen.99596 (Accessed 5th Sept, 2024).
[5] Walter V. Reid, et al, BIODIVERSITY PROSPECTING: Using Genetic Resources for Sustainable Development, World Resources Institute, *Also available at:* https://www.researchgate.net/profile/Sarah-Laird-6/publication/285188831_Biodiversity_prospecting_contract/links/5ec5c506458515626cbbe75a/Biodiversity-prospecting-contract.pdf.

There is also a high incidence of conflict in the relationships among these players, especially in cases where the benefits arising from bioprospecting are not equitably distributed.

IPR IN BIOPROSPECTING

IPR in bioprospecting is usually seen when there is the need to protect inventions actualized through resources of a biological nature often found in native or native regions. Internationally, the Convention on Biological Diversity and the Nagoya Protocol 2010, provide guidelines for access to genetic resources and benefit-sharing. But it is to be noted that these protections do not come without a price, which is often at the cost of the local populace.

Ethical Considerations in Bioprospecting

1. Exploitation of Conventional knowledge and Genetic Resources

One of the major ethical issues involved in bioprospecting concerns the utilization of native knowledge and genetic resources. Many native groups have had their knowledge and resources taken without their prior consent, with or without compensation. The threats from such exploitations could mean endangering the rights of the communities, their cultural identities, and even their very existence.[6]

In 1990, the United States Patent and Trademark Office granted a patent to the American W.R. Grace Company for a methodology wherein extracts of the neem trees were used as a pesticide. The trees had been long used by local communities in India to produce medicines and insecticides. The patent was ethically dubious since it did not recognize conventional knowledge on the part of India's farmers and scientists. This gave rise to what is now known as biopiracy[7], where this term was used by critics to define a situation where commercial entities seek to realize profits through the use of native knowledge without recognition. A set of legal claims and counterclaims supported by the Government of India and other local activists finally led to the revocation of the patent in 2005. Because of this, the case is very

[6] Roger Chenells, *Biodiversity and the Law: Intellectual Property, Biotechnology and Conventional knowledge*, 419, Charles R McMains, 2007.

[7] The unauthorized extraction of biological resources and/or associated conventional knowledge from developing countries, or the patenting of spurious inventions based on such knowledge or resources without compensation are to be term as Biopiracy. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7910072/).

relevant and has brought to the fore the need to ensure that Native knowledge, if used for bioprospecting, is done in a manner that is just and respectful.[8]

2. Issues of Consent and Benefit Sharing

Consent (informed and prior) in this respect would mean bringing to the knowledge of Native Communities the potential inventive use of their genetic resources and obtaining their permission before such usage is done for commercial purposes.[9] Whereas Benefit sharing would entail fair share of profits derived through commercialization of such resources to the natives themselves.[10]

The Biodiverse and Nutritious Potato initiative from the International Potato Center advanced in Peru, Nepal, and Bhutan, is a relevant example of aforementioned concerns wrt bioprospecting and access to genetic resources, benefit-sharing, and IPRs. The initiative encourages the sharing and cultivation of resistant potato varieties to climate change and diseases with equitable benefit-sharing conforming to ITPGRFA[11]. It respects conventional knowledge through participatory breeding and decentralized selection that answer the calls for sustainability and environmental ethics. The project balances innovation, biodiversity conservation, and respect for cultural sensitivity in its commitment to fair access and utilization of genetic resources.[12]

3. Impact on Native Peoples' Rights and Cultural Heritage

Where genetic resources are commercialized with traditional-knowledge, artistic expressions could be degraded or traditional means of subsistence severely diminished. It can also cause

[8] Emily Marden, *The Neem Tree Patent: International Conflict over the Commodification of Life*, BOSTON COLLEGE INTERNATIONAL AND COMPARATIVE LAW REVIEW, http://nationalaglawcenter.org/wp-content/uploads/assets/bibarticles/marden_neem.pdf (Accessed: 02 September 2024).

[9] *Intellectual Property and Bioethics- An overview*, WIPO, Available at: IP and Bioethics-INT.qxd (wipo.int) (Accessed: 5th September, 2024).

[10] *Introduction to access and benefit-sharing*, Convention on Biological Diversity, Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7910072/ (Accessed: 5th September, 2024).

[11] International Treaty on Plant Genetic Resources for Food and Agriculture.

[12] Biodiverse and Nutritious Potato Improvement Across Peru, Nepal and Bhutan, CIP, December 2015, Available at:https://www.fao.org/fileadmin/user_upload/faoweb/plant-treaty/Project-Proposals/W2B-PR-23-Peru_-Technical_Proposal.pdf (Accessed: 5th September, 2024).

trouble in the community when some individuals become recipients of bioprospecting benefits while others do not have that particular privilege.[13]

4. Biodiversity Conservation

The collection of genetic resources from environmentally sensitive ecosystems can result in environmental degradation and put species and ecosystems at risk.[14] Unsustainable bioprospecting activities may cause habitat destruction and loss of biodiversity, impacting not only the environment but also the people with livelihoods dependent on those ecosystems.[15] Ethical bioprospecting should focus on sustainable practices and Conservation programs should be integrated within bioprospecting to ensure the ecological balance is upheld and the rights of those committed to protecting these areas are protected.

STRATEGIES FOR ENSURING EQUITABILTY

Full participation of native communities in decision-making and fair distribution of profits from the commercialization of their conventional knowledge are essential in order not to violate the principle of equity.[16] One of the possible strategies could be the adoption of access and benefit-sharing agreements[17]through the Nagoya Protocol created in 2010. The said agreement would require organizations to take prior informed consent from the Native peoples about using their genetic resources and share the benefits derived thereof.[18]

In addition, to above the model for recognition of collective rights which entails conventional wisdom is regarded as community property instead of being regarded as individual property of an inventor can be considered for implementation.[19] Another model is that of defensive

[13] Das, K., *The Global Quest for Green Gold: Implications of Bioprospecting and Patenting for Native Bioresources and Knowledge*, SOCIETY AND CULTURE IN SOUTH ASIA, (2020) 6(1), 74-97.

[14] *Biodiversity and Ecosystem Health,* SOUTH AFRICA ENVIRONMENT OUTLOOK, Available at: https://www.dffe.gov.za/sites/default/files/docs/part2_biodiversity_ecosystems_health.pdf (Accessed: 5th September 2024)

[15] Ibid

[16] De Jonge, B., *What is Fair and Equitable Benefit-sharing?,* J AGRIC ENVIRON ETHICS 24, 127–146 (2011).

[17] An Access and Benefit Sharing Agreement (ABSA) is an agreement that defines how the benefits from using genetic resources are shared fairly and equitably between the people or countries that provide them and the people or countries that use them. ABSAs are often used in bioprospecting, which is when native knowledge is used to find commercially valuable genetic and biochemical resources. (https://www.cbd.int/abs/infokit/revised/web/factsheet-abs-en.pdf).

[18] *The Nagoya Protocol on Access and Benefit-Sharing*, Convention on Biological Diversity, Available at: https://www.cbd.int/abs/about/default.shtml (Accessed: 05 September 2024).

[19] *Intellectual Property and Conventional knowledge*, WIPO, https://www.wipo.int/edocs/pubdocs/en/tk/920/wipo_pub_920.pdf (Accessed: 05 September 2024)

protection whereby the documentation of conventional knowledge would be made available to the public to prevent others from patenting it.[20]

A noteworthy model is the case of the Arogyapacha. It is well documented for its introduction of the ABS Agreement. In this case, the Kani Tribe of Kerala, India, has traditionally used a wild plant named Trichous zeylanicus commonly known as 'Arogyapacha'. This plant has been used by them for medicinal purposes such as the treatment of stress and fatigue. In the 1980s, scientists working in the region discovered its potential for developing a new drug called 'Jeevani' and commercialized it. While transferring the technology for the production of the drug to the pharmaceutical firm, TBGRI[21] agreed to share the license fee and royalty with the tribal community on a fifty-fifty basis. This was the first ABS prototype in the world. Ultimately, an agreement on benefit-sharing was reached and set a standard for fair compensation regarding native knowledge in bioprospecting activities. At the same time, however, the case did raise concerns over the issue of prior informed consent and whether the benefit-sharing truly reflected the value of the knowledge provided by the Kani people, thereby becoming subject to criticism on the grounds of not yielding good results.[22]

Excerpts issues are common and they have been the cause of almost endless number of arguments about bioprospecting, cultural appropriation of indigenous people, unequal benefit-sharing and traditional knowledge protection.

CASE STUDIES HIGHLIGHTING ETHICAL DILEMMAS IN BIOPROSPECTING

Many case studies[23] pointedly refer to the various ethical issues connected with bioprospecting. One example is the commercialization of *Hoodia*[24], a botanical resource utilized by the San people from Southern Africa to suppress appetite, which raised quite significant ethical concerns. Whereas in the end, compensation was given to the San people, this case highlighted

[20] *Background Brief Conventional knowledge and intellectual property,* WIPO, Available at: https://www.wipo.int/export/sites/www/pressroom/en/documents/background_brief_tk.pdf (Accessed: 05 September 2024).

[21] Tropical Botanical Garden and Research Institute.

[22] The Kani Learning, Down to Earth, Available at https://www.downtoearth.org.in/coverage/the-kani-learning-39208 (Accessed: 05 September 2024)

[23] The Basmati Rice Case is one of the prime illustrations of biopiracy and the ethical issues related to bioprospecting. The case led to a major uproar and it brought up very serious issues about the original farming commodities, intellectual property rights, and exploitation of the smallholder farmers. As a result of the public pressure, parts of the patents were withdrawn, thereby highlighting the need for agriculture self-determination and responsible bioprospecting practices. [Prom-u-thai, C., Rerkasem, B. Rice quality improvement: A review. *Agron. Sustain. Dev.* 40, 28 (2020)]

[24] *Stolen Knowledge: The Hoodia Case*, PUBLIC EYE, 19 September 2001.

a partial problem in ensuring equitable benefit sharing and the need for greater recognition of native rights. In the landmark Case of the *Turmeric Patent* in 1995, two Indian scientists at the University of Mississippi Medical Center were granted a U.S. patent (No. 5,401,504) for the use of turmeric (Curcuma longa) powder to heal wounds. Turmeric has been used in India for centuries for its medicinal properties, particularly for wound healing. This patent was seen as an attempt to monopolize traditional Indian knowledge without any recognition or benefit-sharing with the communities that have long used turmeric for such purposes. In 1996, the Council of Scientific and Industrial Research (CSIR) in India lodged a formal objection to the patent at the United States Patent and Trademark Office. CSIR argued that the therapeutic properties of turmeric had been an integral part of conventional knowledge of India, as evidenced by ancient texts, and is commonly used in a variety of applications in households throughout India. This was considered "prior art"-that is, the knowledge was already in the public domain and not a novel invention. In 1997, the USPTO revoked the patent, finding the claimed use of turmeric was not novel and that the patent was based on conventional knowledge.[25]

IPR AND ETHICAL PRACTICE: NEED TO BE HARMONIZED

The clash between IPR protection and native rights stands at the heart of bioprospecting. IPR offers motivation to innovate, but it can also result in monopolies over resources that form part of a community's cultural legacy. This conflict often grows worse because IPR systems have their roots in Western legal ideas that might not match up with Native ways of seeing the world.[26] Today's IPR systems have big problems when it comes to handling ethical issues in bioprospecting. These systems often put individual inventors and big companies first instead of communities. They're set up to protect business interests. Because of this, they might not recognize the group International treaties, like the Nagoya Protocol and the Convention on Biological Diversity from 1992, have a significant impact on encouraging responsible bioprospecting. These pacts create guidelines to make sure people use genetic resources and

[25] Saipriya Balasubramanian, *Conventional knowledge And Patent Issues: An Overview Of Turmeric, Basmati, Neem Cases,* MONDAQ, available at https://www.mondaq.com/india/patent/586384/traditional-knowledge-and-patent-issues-an-overview-of-turmeric-basmati-neem-cases (Accessed: 07 September, 2024).

[26] *Protecting Community Rights over Conventional knowledge Implications of customary laws and practices*, INTERNATIONAL INSTITUTE FOR ENVIRONMENT AND DEVELOPMENT, Available at: https://www.iied.org/sites/default/files/pdfs/migrate/14591IIED.pdf (Accessed: 07 September, 2024).

conventional knowledge. Article 15 of the CBD lays out principles to control access and benefit-sharing. These principles provide two main responsibilities to government:

1. To set up systems that make it easy to access genetic resources for eco-friendly purposes
2. To make sure users and providers share the benefits of using these resources.

Yet, putting these agreements into practice remains tough due to the persuasive nature of International Law.[27]

CONCLUSION AND RECOMMENDATIONS

The present piece seeks to show the relationship between innovation and ethics in the area of bioprospecting. The use of IPR on the one hand encourages the development of inventions and the commercial exploitation of nature, but, on the other hand, exclusivity cites some serious ethical implications as well, mostly of exploitative nature. IPR practices usually put commercial profits ahead of ethical issues, which makes finding balance between intellectual property rights, native rights, and cultural heritage preservation, challenging.

It is mandatory for the IPR framework to balance innovation with ethical commitment. This would require the IPR regime to be inclusive and show proper respect for conventional knowledge systems and practicing equitable benefit sharing is a start. Also, the stronger participation of the local people in the decision-making process should be pursued to respect their rights and keep their culture alive.[28]

The constant demand of protected product has led to unsustainable resource gathering which further endangers and even threatens extinction of the bio-materials which are the livelihood of the local economy. In most cases the communities who are responsible for the collection of these bio-materials are taken advantage of, they are given minimal compensation, while the middlemen and traders make their profit disproportionately.

[27] *Bioprospecting and Biopiracy*, Novotech, (22 August 2022) Available at: https://novotech-cro.com/faq/bioprospecting-and-biopiracy (Accessed: 07 September, 2024)

[28] Exchanging extremely precious medicinal plants of Himalayas such as the 'yarsagumba' and 'ginseng' from which the region makes money is not only a legal and philosophical issue but can be hazardous. Bio-diversity and local people, whose subsistence depends on those plants, get threatened through over-harvesting, is the primary embodiment for the need of the framework to balance the innovation and ethical commitments. (https://www.downtoearth.org.in/wildlife-biodiversity/himalayan-gold-rush-growing-livelihood-reliance-on-lucrative-and-vulnerable-trade-68453)

Most of the Indian legislations like the Biological Diversity Act, 2002 is bereft of adequate enforcement and it is self-evident by the fact that no real legal case has ever occurred that leaves the issues such as biopiracy and fair benefit-sharing to be addressed. To create an ethical IPR regimen on native bioprospecting, the following solutions can be considered worthy. Firstly, reformed IPR systems should be set up in a way that they, recognize the collective rights of Native communities and secondly, rebuff the exploitation of traditional know-how. Also, ABS agreements should be universally used to make sure respect is given to the IPR rights of natives. Further, there should be more intensive efforts to actively involve and take account of the rights of locals to prior informed consent. The future challenge is to create a bioprospecting program that is innovative, fair, and sustainably ecological. The practice needs to be looked upon by "governments, corporations, and international organizations" as a matter of urgency. They should join in the process of making alterations to the currently existing IPR frameworks, introducing strong ethical standards, and sharing the benefits more equitably. This is speculated to bring bioprospecting to a level in which both the natural environment and the cultural DNA of the Native people are respected, thus leading to resource exploitation to be sustainable and inclusive.