Page 1182 - 1196 **DOI:** *https://doij.org/10.10000/IJLMH.113173*

INTERNATIONAL JOURNAL OF LAW MANAGEMENT & HUMANITIES

[ISSN 2581-5369]

Volume 5 | Issue 3

2022

Biopiracy: International Regimes and Challenges

GAYATRI PRASAD BIRABARA[1] AND ARINDAM SHIT[2]

ABSTRACT

Biopiracy is critical to the conservation of biodiversity because it is a complex issue on which there is no such suitable agreement in the international community. The growing expansion of technology pushed developed countries to protect their technological knowledge, culminating in the adoption of minimum standards for patent law in the World Trade Organization's TRIP'S Agreement. Efforts by such weaker developing countries to address the negative effects of IPRs on developing countries and biodiversity have been far less effective.

The growing concern about the disappearance has resulted in the adoption of various legal instruments such as the Convention on Biological Diversity, TRIPs-World Trade Organization, and so on, but mandatory disclosure could be used to monitor compliance with the CBD and remedy biopiracy. This paper deals with the legal perspectives as well as effective remedy to biopiracy from genetic resources, traditional knowledge, and private agreements has been examined.

Keywords: *Biopiracy, Biodiversity, Intellectual Property, Biological Diversity Law.*

I. INTRODUCTION

"Biopiracy," the term was first developed in 1993 by Pat Roy Mooney, an activist of a Canada based NGO Rural Advancement Foundation International, due to growing frustrations about the appropriation and monopolization of long-held medicinal and agricultural knowledge about nature, as well as the natural resources[3]. The flow of these resources and knowledge, often 'from biodiversity in the South to medicines and cosmetics in the North', has been targeted by NGOs as a hypocritical injustice on the part of corporations and researchers predominantly from Japan, Europe and other parts of the Western Countries[4].

[1] Author is a student in India.
[2] Author is a student in India.
[3] Pat Roy Mooney, 2000, (notes), "the use of intellectual property systems to legitimize the exclusive ownership and control of biological resources and knowledge, without recognition, compensation or protection for contributions from indigenous and rural communities... thus bioprospecting cannot be considered anything but biopiracy."
[4] P R Mooney, 'Why We Call It Biopiracy' in H Svarstad and S Dhillion (eds), Bioprospecting: From Biodiversity in the South to Medicines in the North, 37 (Spartacus Forlag, 2000).

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Although the colonial enterprise of knowledge from plant and animal has been ongoing for centuries, the biopiracy disclosure was generated to illustrate that more recent technological and institutional changes have, the biopiracy discourse arose to exemplify how recent technological and institutional changes have encouraged new inequities while intensifying old ones[5]. Biopiracy has essentially been used as a counter-discourse to intellectual property 'piracy' in the context of the new 'global' intellectual property rules. It is essential to consider that the concept of biopiracy is a multifaceted concept which is being used as a political tool[6]. Nevertheless, given the severity of the issues and concerns surrounding biopiracy, it has been used to describe and criticize several incidents by other individuals and organizations.

Most prominent incident, the Basmati Rice Case which showcased the darker side of the Biopiracy being used as a mere political tool. The 'anti-biopirate' Vandana Shiva attacked the green revolution in 1991, the intellectual property system in 1997 and 2001, genetic reductionism, and her notable activism on several Basmati-related patents has gained international attention. The use of the term "biopiracy" in these contexts indicates that the term has become politicized, reactive, and, in many cases, imprecise[7]. Nevertheless, in addition to the political and NGO-activist responses to biopiracy, indigenous communities, farmers, and local communities have expressed concern about the exploitation of their knowledge and plants, which they have developed over centuries.

With the increasing awareness among the broader public sympathizing NGOs, Activists the biopiracy issue has extended to a larger part. In recent scenarios, the government delegates from different countries have been taking this issue seriously and have made an effort targeting biopiracy has increased the momentum. Biopiracy is clearly a counter-discourse to corporations' complaints concerning intellectual property 'piracy' in the most developed nations. As noted by authors such as Drahos and Braithwaite[8], the discourse of piracy has been conflated to mean the copying of others' intellectual works, whether those authors/creators have registered copyrights in jurisdictions around the world. In addition, Biopiracy has been used strategically in international trade and intellectual property negotiations, due to inequities in trade and technology deals between countries globally.

[5] Our Common Future (World Commission on Environment and Development 1987), also known as the Brundtland Report, http:// www.biodiv.org/convention/convention.shtml. (last visited Nov 12, 2021).
[6] RAFI 'Biopiracy Update: A Global Pandemic', RAFI Communique, September– October (1995).
[7] Vandana Shiva, *Biodiversity and People's knowledge*, *in* BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE 69–80 (2016).
[8] Drahos, P. with Braithwaite, J. Information Feudalism: Who Owns the Knowledge Economy? New Press, New York, NY, (2002).

(B) Research Problem

After an ostensible failure of TRIPS agreement under the WTO regime, in the Uruguay Round of Negotiations, to raise the living standards of developing countries, miserably highlighted social, cultural and widening economic differences. This constitutes the general backdrop that situates the current debate over the issue of misappropriation and exercise off the proprietary rights by the developed nations over the biological material of the developing nations, within the framework of TRIPS. This is what has been labeled as biopiracy, a term that describes the means by which corporations from the developed nations claim ownership of the genetic resources and traditional knowledge and technologies of developing countries. The developing nations are apprehensive that the TRIPS is merely an exploitative mechanism employed to patent indigenous biological material in context the developed nations are concerned regarding the incentive of intellectual protection, the motivation to create, invest and invent will be lost.

This paper aims to briefly examine and analyse the international legal framework on the protection of intellectual property under CBD and TRIPS, and focuses to situate the issues regarding the current debate on biopiracy as inimical to the interests of the developing nations and this paper also aims to provide an analytical analysis of the recent cases involving biopiracy.

(B) Review of related literatures

Biopiracy being a very debatable domain, may author expressed their ideology by means of their articles and books over this issue. Their loopholes in the expression as well as the suggestions has been taken in consideration to develop this instant paper.

Janna Rose, in her article '***Biopiracy: When indigenous knowledge is patented for profit***'[9], explained very briefly that biopiracy is not restricted to drug development only, rather it also occurs in agricultural as well as industrial fields. She also discussed about scientific colonialism and how historically biopiracy linked with it. The author also stated in her article that biopiracy will no disappear soon as many researchers working in this field for crop science, so that they can share genetic sequences making patent claim challenging for big firms.

In another article by **Ankita Sabharwal**, '***Biopiracy in India: Scientific eruption or traditional disruption***'[10], where she discussed about disputes regarding biopiracy. In this very

[9] Janna Rose Chercheuse en Développement durable, BIOPIRACY: WHEN INDIGENOUS KNOWLEDGE IS PATENTED FOR PROFIT THE CONVERSATION (2020), https://theconversation.com/biopiracy-when-indigenous-knowledge-is-patented-for-profit-55589 (last visited Nov 15, 2021).

[10] Biopiracy in India: Scientific eruption or traditional disruption? LEXOLOGY (2020), https://www.lexology.com/library/detail.aspx?g=1c132aa5-97af-4164-af22-ca3c240ab172 (last visited Nov 23, 2021).

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article various naturally occurring products has been objectified to explain the disputes related to them like turmeric dispute, neem disputes, Bt Brinjal disputes ect. Also, she described about the Indian scenario whereby the role of Indian legislature has been pointed out regarding the issue.

Some articles like '***Biopiracy and Intellectual Property Rights***'[11] has raised the concern of patenting of innovations, developed through biotechnology. The Author stated that the many pharmaceuticals, cosmetic and agro food industries spends millions in the research and development for developing products and then subject them to experimentation in society, after that they claim patent on those, based on 'novelties' which affects the traditional knowledge, indigenous community and their cultural heritage for selfish needs. Although bio piracy is still not considered as a crime rather it is viewed as an ethical wrong from ancient time. The author further discussed issue of bio piracy in context of various countries and pointed out the effects of the same.

In a book '***BIOPIRACY: The plunder of nature and knowledge***'[12] by **Vandana Shiva** where she stated that the door to patent the seeds and patent on life are open if developed by genetic engineering. In the 4th chapter of this book author briefly discussed indigenous knowledge and IPR. Whereby she stated that patenting process as well as the products derived from plants and indigenous knowledge is a major issue in the field of IPR. Further the author in this very chapter established differences between bioprospecting and people's knowledge, by virtue of which she stated that use of biodiversity is well known by the communities from where the knowledge is extracted through bioprospecting contracts. So, metaphor of bioprospecting hides the prior use, knowledge and other rights associated with it.

In another book '***Global biopiracy: Patents, Plants and indigenous knowledge***'[13] **by Ikechi Mgbeoji**, deals with legal control and ownership over plants and indigenous knowledges. In the 2nd chapter of this book the Author discussed about various theories of patents and historical evolution and further he claimed that Patents also serve as a legal anchor for the state's conceptions of distributive justice and public morality, or public order. According to him, as biotechnology becomes a more important component of national wealth, and as global economic interdependence expands trade frontiers, 200 the economic rent to be collected by a stringent and global application of patents on indigenous biocultural resources becomes a

[11] Jyoti Goel, BIOPIRACY AND INTELLECTUAL PROPERTY RIGHTS, WITFEEDER (2020).
[12] Vandana Shiva, *Biodiversity and People's knowledge*, *in* BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE 69–80 (2016).
[13] Ikechi Mgbeoji, *Patents, indigenous, and traditional knowledge and biopiracy*, *in* BIOPIRACY: PATENTS, PLANTS, AND INDIGENOUS KNOWLEDGE (2006).

compelling national priority for industrialised states.

Further in a journal article, '***Patents and Biopiracy: The Search for Appropriate Policy and Legal Responses***'[14], by **Hamdallah Zedan**, author dealt with the increasing disputes relating to genetic resources and traditional knowledge and IP right related to it. By means of his research, he concluded that, conservation, sustainability, ownership, governance, and equity issues and the international intellectual property rights regime will need to address legitimate concerns about access to and use of genetic resources and traditional knowledge. Regional and national developments contain critical lessons about the direction of de sired change and should inform international policy decisions.

(C) Objectives

- To critically analyse the legal backdrops in the substantive laws relating to Biopiracy.
- To draw out the implication of model laws dealing with Bioprospecting and Biopiracy.
- To discuss about the initiatives taken by International Organisations like United Nations and World Trade Organization.

(D) Hypothesis

Although the Biopiracy is surrounded by substantial law, but the researchers believes that the issue at hand is not properly dealt with and further there are lacunas in the model laws which needs to be amended.

(E) Scope

The scope of the paper is restricted to the legal backdrop regarding the biopiracy, and data has been collected from relevant international agreements and treaties. This has been analysed with an international viewpoint and extended to biopiracy related issues in those countries where this issue has become a major concern. Further the decisions, information and legal implication is limited to the date of publication. Any decisions, law, and other data which may relevant after the said date is not a covered under the scope of this paper.

(F) Research methodology

Doctrinal methodology is followed throughout the paper. Secondary source has to be used for the absence and impossibility of the first-hand survey and information. The content is descriptive and analytical. This paper also analyses the potential of various agreements, model laws and negotiations as well as their limitations.

[14] Hamdallah Zedan, *Patents and Biopiracy: The Search for Appropriate Policy and Legal Responses*, 12 THE BROWN JOURNAL OF WORLD AFFAIRS 189–205 (2005).

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II. MAIN BODY

With the increasing debate over the ownership, number of agreements, recent treaties and international laws has shifted towards a regime that protects exclusive individual property rights. The Intellectual Property Agreement discussed below has focused on the exclusive rights of inventors, plant breeders and the researchers has tried to focus on the loopholes which has been creating the issues like biopiracy and bioprospecting.

(A) The Convention on Biological Diversity

The Convention on Biological Diversity was drafted at the Rio Earth Summit in 1992 and came into effect in 1993. The objectives of the Convention, "are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding."

The Convention establishes and binds its parties to a number of essential biodiversity principles. Firstly, it supports the sovereign rights of states over natural resources (Article 15). As a result, state parties have the authority to set access rules for biological resources. Because genetic resources (seeds, cuttings, and samples) are replicable and many plants or genes are not unique to a single country (either naturally or through commerce), access rights are often territory-limited and only as good as the country's controls (such as customs). Extraterritoriality has been a constant concern in biopiracy instances involving several countries with distinct laws. Questions about plant beneficial features, bioresources, DNA, and biochemicals have complicated the access and benefit-sharing situations that may occur. For instance, a plant may be endemic to several countries, but the knowledge of its use for medicinal purposes may in some cases be isolated to one ethnic group or one local community. However, as communication technologies develop and spread globally, information paths are opening up via which any remaining distinctly local knowledge, even in remote regions, may become a rarity.

The scope of Article 15 of the CBD is wide, it requires a party to get a prior consent of the Contracting Party to access the genetic resources or depends on the party. Furthermore, ad hoc working group and Bonn Guidelines has made an emphasis on extending prior informed consent to the local custodians on genetic resources and traditional knowledge holders through national laws. However, the Bonn Guidelines are not legally binding and furthermore, the parties face great difficulty while getting consent and getting on the same ground for agreement

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with the working groups of CBD[15]. The Article has also specified the need of fair and equitable benefit-sharing of the research resourced, development and commercialization of genetic resource innovations. According to the CBD and the Bonn Guidelines, benefit-sharing agreements must be achieved under mutually agreed terms[16]. However, there is always a possibility of unequal power relation between researchers and the providers of genetic resources.

The CBD has also directed that each Contracting Party shall, as far as possible and as appropriate, "*Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.*"[17] The safeguarding of biological resources and traditional knowledge involves a number of difficult issues. There is an international framework in which many of the CBD parties and other interest groups are attempting to prevent foreign researchers from engaging in 'biopiracy.' Because majority of the world's biodiversity is biogeographically distributed in the tropics, a group of Like Minded Megadiverse Developing Countries has created a negotiating group that has been strongly negotiating towards the blockage of biopiracy. At the same time, many of the same countries are attempting to promote or at least control access to bioresources on which traditional knowledge exists in their countries, with the goal of reaping different societal and economic benefits. The aforementioned principles of access and benefit-sharing, as well as free prior informed permission, all provide significant tools for protecting and promoting traditional knowledge. However, much more intricate considerations are being addressed in relation to traditional knowledge.

Some of the more sensitive issues that have proven complex and difficult to resolve concern the respect of indigenous and traditional local groups' customary protocols, cultural concerns over secret or sacred knowledge with spiritual connections to nature, and the protection of these

[15] Cabrera Medaglia, J. Study on the Relationship Between an International Regime on Access and Benefit-Sharing and Other International Instruments and Forums that Govern the Use of Genetic Resources, submission to the CBD Secretariat, (2009).
[16] CBD Secretariat, Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, Secretariat of the Convention on Biological Diversity, Montreal (2002).
[17] Cabrera Medaglia, J. Study on the Relationship Between an International Regime on Access and Benefit-Sharing and Other International Instruments and Forums that Govern the Use of Genetic Resources, submission to the CBD Secretariat (2009).

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groups' rights in general. Given the range of cultural and jurisprudential diversity reflected by these many groups, developing international rules that may address their concerns may be very difficult. As a result, there is substantial room for innovative national and local programmes to conserve and promote traditional knowledge, in addition to the CBD's and national governments' efforts to regulate biopiracy.

(B) The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights

Following the Uruguay Round of Multilateral trade Negotiations, the World Trade Organization was established in 1995. In the suit of the legal texts that form the mandate of the WTO, the Trade-Related aspects of Intellectual Property Rights (TRIPS) Agreement was included, representing a shift from the goods-only trade agreements of the GATT.

The TRIPS agreement deals with a range of intellectual property rights including copyright, trademarks, geographical indications (GIs), patents and plant-variety protection rights. While WTO members are granted some IPR exclusions for plants and animals, the flexibility is limited. Members are required under the TRIPS Agreement to offer either patent and/or sui generis protection for plant types. Aside from these duties, numerous member states are now seeking clarification on CBD's compatibility.

Patents, Plant-Variety Protection or Sui Generis Systems

Article 27.3(b) of TRIPs, "*plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.*" Basically, members must protect plant varieties either through the use of patent protections or *sui generis* system of their protection.

The drafting of Article 27.3(b) in this term has reflected some conflicting concerns. These included the significant interests of some developed countries in guaranteeing that biotechnological innovations might be protected; some disparities in the scope of protection among this group of countries; and many developing countries' worries regarding the patentability of life forms. Until recently, the European Union and its member states were more unwilling to offer patent protection, preferring plant-variety protection as codified in the International Union for the Protection of New Varieties of Plants. Prior to the implementation of TRIPS, the majority of poor and least-developed nations had neither system in place. As a result, many developing countries have sought to comply with this WTO mandate by the year 2000, while least developed countries have until 2013. With this ongoing, internationally led

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expansion of private property rights in plant varieties, there are several concerns. One of such is, the expanding ability for foreign researchers to extract, develop, and ultimately protect plant and bioresource inventions as exclusive private rights is of particular importance here. With the proliferation of national plant-variety protection systems, there may be more opportunities for researchers to pursue private rights in plant-related advances, leading to an increase in biopiracy[18]. However, because of the growing worldwide concern about biopiracy, proper international systems may be able to limit bioprospecting operations that are regarded inappropriate and labelled as biopiracy. Other consequences of plant-variety protection systems could include the promotion of genetically uniform monocultures and limits on farmers' rights.

Although several countries have quickly constructed Union for the Protection of New Varieties compliant plant-variety protection systems, the wording of Article 27.3 allows for considerable flexibility. There is no more clarification in the TRIPS Agreement as to what makes an 'efficient' sui generis system, therefore there is substantial room for the establishment of utterly unique national systems. Furthermore, TRIPS do not clarify on the term "plant varieties," and it does not oblige countries to join Union for the Protection of New Varieties or to draught legislation that is equivalent to the Union for the Protection of New Varieties Acts[19]. It is widely agreed that, in order to be a successful sui generis system, plant-variety protection must be provided as a system of legal rights (e.g., intellectual property rights or liability laws), which has traditionally been similar to existing systems such as Union for the Protection of New Varieties. It is generally accepted that to be an effective sui generis system, plant-variety protection must be afforded as a system of legal rights (e.g., IP rights, or liability rules), which have typically been similar to existing systems like Union for the Protection of New Varieties)[20]. Also, it is generally assumed that the system must accord to principles of national treatment and most-favoured-nation treatment, and must provide some sort of enforcement mechanism.[21] Because TRIPS only establishes a set of minimum protection requirements, countries are not prevented from developing sui generis systems that may include provisions for farmers' rights, respect for customary rights of local groups, protections for traditional knowledge, and the right to accrue benefits when plant genetic resources are accessed. As a

[18] Rangnekar, D 'Indications of Geographical Origin in Asia: Legal and Policy Issues to Resolve', in Meléndez-Ortiz, R. and Roffe, P. (eds) Intellectual Property and Sustainable Development: Development Agendas in a Changing World, Edward Elgar, Oxford, (2009).

[19] Dhar, B., Sui Generis Systems for Plant-Variety Protection: Options Under TRIPS, Quaker United Nations Office, Geneva, (2002).

[20] DAN LESKIEN & MICHAEL FLITNER, INTELLECTUAL PROPERTY RIGHTS AND PLANT GENETIC RESOURCES: OPTIONS FOR A SUI GENERIS SYSTEM (1997).

[21] UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT (2005).

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result, the sui generis systems that are built could be designed to prevent or at least restrict biopiracy instances. In India, for example, a non-Union for the Protection of New Varieties sui generis plant-variety protection law is combined with a biodiversity law to ensure that the conservation, development, and innovation of plants and biological resources, whether through modern or traditional means, is protected through both individual and community rights.

The scope of Article 27.3(b): There is a serious requirement to review the Article 27.3(b) of the TRIPS. As when the review was expanded by the Doha Declaration under Development Agenda to examine the relationship between TRIPS and the CBD[22], and the protection of traditional knowledge and folklore, loops holes were found relating to the issue of Biopiracy.

Recently, several recommendations have been made, especially by developing countries, for patent applications to reveal the country and source of origin from where genetic materials were sourced, as well as evidence of prior informed permission and evidence of fair and equitable benefit-sharing. These negotiations have been going on since 2005 and look to be making some headway. Countries such as the United States have frequently claimed that a disclosure-of-origin patent requirement would slow down the patent examination process and burden inventors, and that benefit-sharing arrangements should be arranged through contracts on a case-by-case basis.

III. SUGGESTION

Biopiracy inevitably must be addressed with through actions at various governmental scales. The majority of biopiracy problems include global transfers of biological resources and traditional knowledge, which frequently results in intellectual property protection in foreign jurisdictions. As a result, it is critical to address biopiracy issues on a global scale. Attempts have been made in continuing talks surrounding international treaties and conventions such as the CBD to transparently control these international transfers. Furthermore, WTO-TRIPS Council debates are addressing concerns linked to intellectual property rights, genetic resources, and traditional knowledge. These international mechanisms and tools are likely to play an important role in preventing biopiracy in the coming years, but they may also serve broader roles in improving patent quality, promoting innovations derived from traditional knowledge, and potentially improving regulation of bioprospecting activities.

A number of regional efforts involving biological resources and traditional knowledge have been pursued in order to address challenges of particular importance to specific areas or

[22] Brazil, India and others, The Relationship Between the TRIPS Agreement and the CBD: Checklist of Issues, (2004).

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countries. These have been negotiated in areas of common biogeographical interest, where there are common challenges concerning the protection and promotion of traditional knowledge and community rights. These model laws have been proposed to encourage regional consistency in dealing with bioprospecting and benefit-sharing concerns, as well as to aid governments in developing national laws. They were conceived as a means of establishing a regional body to coordinate issues of intellectual property and traditional knowledge[23]. Furthermore, there are several significant non-legally binding agreements or pacts formed outside the UN framework of international law, in which indigenous and local peoples were key contributors and expressed concerns about intellectual property provisions on traditional knowledge and biological resources[24].

Further the expanding scope of Article 27.3(b) of the TRIPs have made some substantial advancement towards a patent requirement that disclose the source and origin of genetic resources used in an invention. The main contention was regarding the reduction in the possibility of patent based biopiracy[25]. Many Countries have also outlined the primary issues surrounding the necessity to mandate disclosure of the source and country of origin of biological resources and traditional knowledge employed in an invention as a patent requirement, as well as evidence of prior informed consent and benefit-sharing. In reply to the question many countries have suggested that failure to disclose this information should result in the patent not being granted; however, if the patent is granted and wrongful disclosure is discovered, the patent may be revoked, the rights transferred to another entity, or the scope of patent claims narrowed to exclude the parts of the claim of concern. They also stated that the burden of evidence should be placed on the patent applicant, and that the disclosure of origin requirement should be made mandatory. They suggested that this should be incorporated as an adjustment to current provisions or as the addition of a new item to the agreement[26]. Still there has been a hard line in these negotiations, arguing g that a 'disclosure requirement' would cause unnecessary burdens to the patent system and be detrimental to technological development and

[23] Kuanpoth, J. 'Closing in on Biopiracy: Legal Dilemmas and Opportunities', in Melendez-Ortiz, R. and Sanchez, V. (eds) Trading in Genes: Development Perspectives on Biotechnology, Trade and Sustainability, Earthscan, London, pp139–52, (2005).

[24] Laird, S.A. and Noejovich, F. ,'Building Equitable Research Relationships with Indigenous Peoples and Local Communities: Prior Informed Consent and Research Agreements', in Laird, S. (ed.) (2002) Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice, Earthscan, London, (2002).

[25] Norway ,Amending The TRIPS Agreement to Introduce an Obligation to Disclose the Origin of Genetic Resources and Traditional Knowledge in Patent Applications: Communication from Norway,(2006).

[26] Norway, The Relationship between the TRIPS Agreement, CBD, and Protection of Traditional Knowledge — Amending the TRIPS Agreement to Introduce an Obligation to Disclose the Origin of Genetic Resources and Traditional Knowledge in Patent Applications — Answer from Norway to Questions Posed by Switzerland in the TRIPS Council, (2007).

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investment. Some of the specifics surrounding a disclosure obligation are still being worked out. If the disclosure requirement is a basic explanation of the contents' lawful source and country of origin. Finally, a generic certificate indicating prior informed consent and/or permitted transfer of genetic resources (and accompanying traditional knowledge) may be necessary. Again, this may be a basic and brief document that researchers are required to receive as part of their import and export permissions in most nations. In terms of prior informed consent for the documentation of traditional knowledge, most respected research organisations in the industrialised world currently require it. As a result, requiring disclosure appears to mainly deter the more dubious research organisations that do not seek prior-informed consent or sign material transfer agreements.

For researchers, requiring evidence of a benefit-sharing arrangement within the disclosure-of-origin regulations may be more difficult. The problem is that the researchers asking for the patent have not yet commercialised the product or determined whether it is suitable for public use (for instance, if it is a pharmaceutical, it would have to be clinically trialled for human use). As a result, it is likely that requiring researchers seeking a patent to commit to share advantages through royalties, milestone payments, knowledge transfer, and other provisions if the innovation is economically viable is a better alternative. Although this provides less confidence to provider organisations, it may also prevent unreasonable expectations from being raised.

It has often been argued that in order to have any substantial impact, the disclosure-of-origin rule must be mandatory. There will most likely be a reliance on the applicant's good faith regarding biological resources and/or traditional knowledge involved, the source and country of origin, and evidence of prior-informed consent and benefit-sharing implying that the requirement's effectiveness will be contingent on the patent applicants' honesty. The publication of this information is likely to be conditional on the patent's successful issuance. The primary developing country proponents of the requirement argue that when an applicant fails to disclose fully or partially reveals this information then the patent should be refused or suspended until such information is provided. If a patent is awarded but later shown to be based on false or intentionally omitted facts about the source and country of origin, prior-informed consent, or benefit-sharing agreement, the patent should be cancelled. However, the negotiating countries must strike a balance between the deterrent of biopiracy and the blatant deterrence of research that could lead to valuable foods and medicines based on biological resources and traditional knowledge. A disclosure requirement should not be so stringent that it discourages this type of research. As a result, it is critical to decide the 'appropriate' level of detail that should be required of patent applicants.

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There have also been many suggestions to provide Geographical Indication tag to protect traditional knowledge.[27] As GIs are intended to reward goodwill and reputation created or built up by a group of producers over many years, and in some cases over centuries. GIs also lend themselves better to communal organization than other IPRs, being advantageous in the traditional knowledge context where such knowledge often originates or is held by specific communities. If a community in a specific geographical location has maintained methods of production of certain products over time, which gives that product a certain quality, then that community would likely be eligible for GI protection of the product. Geographical indications have the added benefit of connecting traditional practises to location and nature, which may be compatible with the worldview of many indigenous and local cultures[28]. Because of the convergence of sociocultural and environmental elements, as well as the fact that they safeguard community rather than individual interests, there is increased interest in GI protection for products such as rooibos tea and basmati and jasmine rice. While GIs are unlikely to prevent biopiracy in most circumstances, they may lower the likelihood of false trademarks being granted and provide a vehicle for promoting conventional products to home and export markets.

At the international level, there are also efforts to guarantee that indigenous rights are honoured, including the appropriate protection and promotion of traditional knowledge. The United Nations Declaration on the Rights of Indigenous Peoples was recently endorsed by the UN General Assembly at its 107th plenary meeting in September 2007, and it represents a significant moral and political step forward in the campaign for indigenous rights. The statement includes significant measures for the protection of human rights, including fundamental freedoms, non-discrimination, self-determination, association, cultural rights, land rights, labour rights, and economic rights of indigenous peoples and persons. Notably, the statement includes several articles specifically addressing traditional knowledge and customary norms, the right to practise and renew cultural traditions and customs, as well as spiritual and religious traditions, customs, and ceremonies[29]. These provisions on intellectual property, traditional knowledge, and other related issues are significant declarations that should serve as a moral, if not legal, deterrent to crimes such as biopiracy. More broadly, the declaration is

[27] Amina Pollard, DOWNES, B. J., ET AL. 2002. *MONITORING ECOLOGICAL IMPACTS: CONCEPTS AND PRACTICE IN FLOWING WATERS.* CAMBRIDGE UNIVERSITY PRESS, NEW YORK, NEW YORK, USA. CONSERVATION ECOLOGY (2003), https://www.ecologyandsociety.org/vol7/iss1/art10/ (last visited Nov 17, 2021).

[28] Rangnekar, D, 'Indications of Geographical Origin in Asia: Legal and Policy Issues to Resolve', in Meléndez-Ortiz, R. and Roffe, P. (eds) Intellectual Property and Sustainable Development: Development Agendas in a Changing World, Edward Elgar, Oxford, (2009).

[29] Posey, D.A. (ed.), Cultural and Spiritual Values of Biodiversity, United Nations Environment Programme, Nairobi, (1999).

likely to raise pressure on national governments to acknowledge the full range of indigenous peoples' rights. The declaration's acceptance is unlikely to be a panacea for indigenous challenges, but it may increase the moral and political clout of indigenous attempts to win fair and equal rights. As a result, if basic respect for the rights of marginalised indigenous peoples is achieved, they will have more opportunity to define their own futures, including the protection of their own knowledge.

IV. CONCLUSION

Biopiracy symbolises the abuses, contempt, and neglect that have long been displayed by colonial powers and the industrialised 'West' for many indigenous communities, farmers, organisations that maintain traditional practises, and across broad populations in the developing globe. Biopiracy has significant ramifications for local producers and research in developing countries and distant places; in terms of cultural impact, it parallels a longer history of colonial abuse, albeit through different ways. The biopiracy cases demonstrate an epistemic hypocrisy in which scientists use old knowledge and advances while dismissing such knowledge as unworthy of acknowledgement. Furthermore, biopiracy must be appropriately addressed in the patent and broader intellectual property systems (to prevent 'nonpatent biopiracy,' as well as through appropriate methods for biodiversity control and transfer. Along with technical and legal procedures, various re-conceptualizations are required, notably with relation to the concept of the "public domain."

Furthermore, we need to recognize that we don’t have only one public domains, in the context of biopiracy, we usually refer to global transactions and, as a result, an international public domain that is ultimately made up of collections of national public domains. In the context of biopiracy, we typically refer to transnational transactions and, as a result, an international public domain that is ultimately made up of collections of national public domains. They are also influenced by the social environment's implications for the application of laws. These varied jurisdictional views of the public domain are known to international policymakers. Furthermore, prior art databases may assist examiners in determining whether patent applicants are improperly exploiting traditional knowledge that has been deemed as 'public domain' and hence publicly available to use. However, these are narrow technical measurements that are unlikely to yield more sophisticated interpretations of where there are public domain limits, what knowledge has been unlawfully divulged, or where knowledge is sacred or secret, among other crucial distinctions.

What is really required is a more culturally informed understanding knowledge domains (rather

 [ISSN 2581-5369]

than 'public' domains) that are governed by both formal rights and customary norms and regulations. Territories, but also cultural boundaries or borderlines such as language, beliefs, values, religions, and practises, influence these knowledge domains. These domains are not neat or precisely defined, and they do not remain constant over time and place. They also do not share biogeographical distributions of plants, animals, and other biological resources, therefore a number of overlapping or contiguous knowledge domains may regulate individual species and plant variations. Some knowledge domains and biological resources may be quite large and 'public,' whilst others may involve smaller populations and be kept secret by specific groups.

Certain pieces of knowledge, as well as certain plants or creatures, may be sacred to certain groups, as informed by religion, rituals, and folklore. This cultural diversity, as it relates to knowledge domains, should be respected for the benefits it provides for self-determination and identity, societal dynamics, creativity, and larger human benefits. As a result, indigenous and local groups, as well as those who interact with them, should aim to preserve and deepen awareness of their specific domains of customary knowledge. Making researchers and the general public comprehend customary knowledge domains is not going to be easy. These customary knowledge domains not only operate differently in different regions, over time and place, but they also necessitate re-conceptualizations of scale and authority. Customary knowledge domains also function on other scales and jurisdictions that many in the global north may find difficult to imagine, recognise, or accept. These kinds of customary rules governing knowledge domains are difficult to reconcile with Western models of governance or even Western modes of thought. As a result, recognising conventional knowledge domains and helping the general public better grasp complicated regulatory systems at conceptually complex and different scales remains a difficulty.

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 [ISSN 2581-5369]