
BIOPIRACY OF GENETIC RESOURCES - ROLE OF THE THREE-TIER STRUCTURE IN REGULATING ACCESS - POTENTIAL CONFLICTS BETWEEN THE NEW SYSTEM AND IPR INTERNATIONAL INSTRUMENTS

Charuprita G, BA LLB (Hons.), Alliance University

ABSTRACT

In the view of erroneous granting of patents with over diligence or no diligence to novelty and inventiveness criteria for patenting systems, the serious deficit in access and benefit sharing mechanisms pertinent to genetic resources and the use of traditional knowledge without due recognition to its people, and the erratic negotiations entered into by the government agencies and other private individuals to gain access to the genetic resources, there exists a lacunae in the above mentioned areas with respect to genetic resources and their patenting uses. A unified international instrument to curb biopiracy and protect indigenous people's sustenance, is yet two in the bush.

Further, this paper aims at analysing the challenges the state biological diversity board and the national biological diversity board face in the course of regulating access to the traditional knowledge and the exploitation of genetic resources with reference to the new system of international cooperation agreed upon by the parties to the convention, from a bird's eye view.

Key Words: Biopiracy, Genetic Resources, Three-Tier Structure, Regulation, Access and Benefit Sharing Mechanisms, State Biological Diversity Board, National Biological Diversity Board, Global Patent Policies, Realist Perspectives, Bio-colonialism, Genetic Information Disclosure

INTRODUCTION - GENETIC RESOURCES IN THE LIGHT OF IP - PATENT GRANTS

Genetic resources are the functional units of the natural environment, that supports life sustenance. The summation of plants, animals, microbial and other biodiversity elements or genetic sequences form the genetic resources. Biodiversity can be secured by means of enabling in situ conservation of the plant and animal species, so as to protect genetic resources from the undue commercial usage patterns and the threats caused thereby and mainly to protect it from under the umbrella of its maintenance. This primacy laid on conservation of genetic resources assures judicious exploitation of those resources in the present and also save for the future. One can surely participate in the benefits derived from the use of genetic resources through research and discovery, by using the material, to the extent allowable, so that there remains sustainable development. The matter of innovation in modern life sciences, has paved way to IP ownerships and especially in patents granting serials and, issues in granting mechanisms of the same which has witnessed several lacunae stages in disclosure requirements to get the researched innovation in genetic resources patented. With respect to the access and benefit sharing framework of CBD (Convention on Biological Diversity, effectuated from 1993), the need to change or bring in protocols to check on erroneously granted patents was necessitated. This eventually leads to curbing the openings to think over and innovate in the field of life sciences, as is so deliberated by the aims of IP (Intellectual Property) and its emergent affirmations as an upcoming field. Studies reveal that research and the nation state are prone to limit biodiversity researches in developing countries because of access regulation of genetic resources.¹ The sustenance of indigenous habitats reliant on genetic resources and their produces are put to stake when proper disclosure of obtaining the GR (Genetic Resource) is pirated. Thus the mandatory disclosure of the origin of the GR is widely professed to be accepted at present. Thereby, the path of unethically restraining access and benefit sharing of these resources is the ultimate monopoly discord of IP.² Pedantically, the details are outgrown and needs focus on it to regain the inertia to regularise and regulate procedural and troubleshooting mechanisms.

¹ Alejandro Grajal, *Biodiversity and the Nation State: Regulating Access to Genetic Resources Limits Biodiversity Research in Developing Countries*, Wiley for Society for Conservation Biology, Jstor (1999)

² Roman Cholij, *In Search of Ethical Solutions to Global IP Discord*, Patents on Life: Religious, Moral, and Social Justice Aspects of Biotechnology and Intellectual Property , 209-226, Cambridge University Press

In the view of erroneous granting of patents with over diligence or no diligence to novelty and inventiveness criteria for patenting systems, the serious deficit in access and benefit sharing mechanisms pertinent to genetic resources and the use of traditional knowledge without due recognition to its people, and the erratic negotiations entered into by the government agencies and other private individuals to gain access to the genetic resources, there exists a lacunae in the above mentioned areas with respect to genetic resources and their patenting uses. A unified international instrument to curb biopiracy and protect indigenous people's sustenance, is yet to be implemented. Thus, the three-tier structure and the function of administration and controlling bio pirated resources are questionable due to the increase in the biopiracy rate despite the encrypted system and stringent rules to curb the same. The paper objectivises to analyse the lacunae in the three-tier structure in the circumspection of examination and granting of patents, inspite of which, biopiracy is on the rise. Thus, despite the encrypted system and stringent rules to curb biopiracy, what lacunae is faced by the three-tier structure, i.e., the litigating body and the international intervention to enhance security against biopiracy of genetic resources? It can be hypothesised, in order to form a base for the research that lack of vigilance and supervision on the examination of the background of genetic resources and the traditional knowledge behind those applications is the reason for rise in biopiracy of genetic resources.

LITERATURE REVIEW

- **Alejandro Grajal, Biodiversity and the Nation State: Regulating Access to Genetic Resources Limits Biodiversity Research in Developing Countries, Wiley for Society for Conservation Biology, Jstor (1999)**

This article focuses on the regulation to genetic resources' access was in view of protecting the essence of resources prevalent and ensuring equitable distribution of the benefits derived from its usage. Stringent regulatory framework to permit the access to genetic resources was seen to, in order to fulfil its original intent. Prompt and accurate information about the genetic resources intended to be used up and the participation of local communities in it play a vital role in granting access to the GRs. This permit system though, commendably implementable, requires attention in its actual implementation.

- **Jacques de Werra, Fighting against Biopiracy: Does the Obligation to Disclose in Patent Applications Truly Help, 42 VAND. J. Transnat'l L. 143 (2009)**

The enumerations in this article concentrate on the aspects of the fast approaching improvements in the biotechnology and world trade rules have compounded the need to regulate and control the access to genetic resources. The unsanctioned collection and exploitation of indigenous genetic resources or bio resources by individuals or corporations for commercial utilisation is biopiracy. That means that the alteration in access and benefit sharing agreement of the GRs amongst nations is the evident form of serious exploitation of those resources by those corporations or individuals posing the genetic resources to be the subject matter of their research.

- **Alejandro Madrazo, Biocolonialism: TRIPs and the Genetic No Man's Land, 25 GEO. INT'L ENVTL. L. REV. 487 (2013)**

Fulcrums of this article lay its foundation on the point that within a legal framework, genetic privacy must be considered a fundamental right, and individuals should be able to block or seek redress for invasions of their genetic privacy by other people and by the government. Rules protecting the privacy of genetic information are intended to prevent, lessen, or eliminate negative consequences of the new genetics. Even if one accepts that privacy is a fundamental value, it does not follow that privacy is an absolute value.

- **Charles R. McManis, Intellectual Property, Genetic Resources and Traditional Knowledge Protection: Thinking Globally, Acting Locally, 11 CARDOZO J. INT'L & COMP. L. 547 (2003)**

The point well established in this article is that the mobilisation to confront biopiracy due to the corporation and its activities to procure IP rights with undue influence unto the officials, is witnessing an uphill now. The concept of 'biodiversity belongs to the commons' urges every single individual to protest and regain their rights over common usage and protection. Hence, it is clear that nobody can misappropriate or seek ownership over that which belongs to the community. This notion is prevalent and increase the growth index of indigenous people and also foresee future prospects to business industries, which it is possible to obtain a patent only thorough proper and requisite authenticity in their research.

ACCESS TO GENETIC RESOURCES AND LEGISLATIVE PARALYSIS TO BIODIVERSITY RESEARCH DEVELOPMENT

The habit of acclaiming a country's genetic resources as its patrimony and provide guidelines

on its usage and access to the biological resources was necessitated on the grounds of a bio project's nuances and regulation essentials. This regulation to genetic resources' access was in view of protecting the essence of resources prevalent and ensuring equitable distribution of the benefits derived from its usage. Stringent regulatory framework to permit the access to genetic resources was seen to, in order to fulfil its original intent. Prompt and accurate information about the genetic resources intended to be used up and the participation of local communities in it play a vital role in granting access to the GRs. This permit system though, commendably implementable, requires attention in its actual implementation. Most important, the undermine of a nation's capabilities on bio-technicalities and resource generation in the environment add to the access regulation decisions. The information on genetic resources and their access needs appropriateness and authenticity, which subsequently would lead to judging and anticipating the nation's ability to decide upon the the accessibility rights of the genetic resources. Also that the prospecting of bio-resources are a possibility only when statutory definitions and meanings are specific and clear. Hence, the ascertainment of an activity as research or not, lies in its proposal enclosing true and fair information of the genetic resources proposed to be put into use. This also solves bio prospecting criteria fulfilment. So, it will require that every biodiversity research should undergo a centralised scrutiny to check and approve on the aspects of its objectives. A continuous series to proposals of evasion of such a mechanism to advance quantum leaps in the genetic resources usage would lead to cumbersome exploitation of those resources and undue and undesired manipulations with respect to the existence and replenishment of the genetic resources.³

It so happens that, erratic negotiations are entered into by the government agencies and other private individuals to gain access to the genetic resources. The development of such cumbersome, erratic, and less transparent permit processes, devised by the Government, can produce a lethargic effect on the correction procedures and granting ways thereby creating duplicity in the work and straight away biopiracy springs. Instead of focusing on centralised government controls and trade secrets, developing nations should actually foster the creation of an accessible knowledge base of their biodiversity. Better and more knowledge will result in better control over access. This very thought of treating biodiversity and the resources as

³ Supra note 1

knowledge and trade secrets is surely to lead the world to a detrimental path and will hamper reasonable controls.⁴

BIOPIRACY - ESSENCE AND REALIST PERSPECTIVES

The concept of traditional knowledge is one of the most respectable area which has been continuous since generations mainly for the good of human race which is carried on by indigenous people of a society. These knowledge packages include various naturally available resources and is used for medical researches and such purposes, also considering India, the birthplace of Ayurveda. The dilemma surfaces when such knowledge unethically procured by outside players and applied for their own selfish advantages, patented without even acknowledging them as true sources. Such misappropriation of genetic resources and natural species of genetic importance which is traditional knowledge is known as biopiracy.⁵ The fast approaching improvements in the biotechnology and world trade rules have compounded the need to regulate and control the access to genetic resources. The unsanctioned collection and exploitation of indigenous genetic resources or bio resources by individuals or corporations for commercial utilisation is biopiracy. That means that the alteration in access and benefit sharing agreement of the GRs amongst nations is the evident form of serious exploitation of those resources by those corporations or individuals posing the genetic resources to be the subject matter of their research. Various governments have been seeking to persuade non adherence to IP driven policies towards genetic resources and its usage restrictions. These far reaching IP rules to grant patents whilst checking the origin of such genetic resources proposed so for the grant is serving unimaginable threats to developing countries as their staple reliance is on those naturally available resources.

The Nagoya Protocol, on access and benefit sharing of the fruits of the bio resources, under the CBD, seemingly addresses and sets out biopiracy issues and nations are wanting to adhere to those propositions so a stop prevent any country's resources to be disproportionately or excessively used up and taken for granted.⁶

⁴ Supra note 3

⁵ Hardik Vyas, *Biopiracy: The eclipse of Indigenous Knowledge in India*, International Journal of Law, Jgate (2020)

⁶The Greens/EFA in the European Parliament, *Genetic Resources and Biopiracy*, <https://www.greens-efa.eu/en/article/news/genetic-resources-and-biopiracy>, accessed on 03/07/2021

Besides all this, the palavers of IP regime being so broadly paced with free and fair nature of evolving in the current scenario, it still has paved way to the misappropriation of genetic resources and the patenting of GRs and the relevant technology associations and affiliations with commercial intent. Recent attempts to gain monopoly over misappropriated GRs is the greatest concern and various negotiations are initiated to proceed with an effective and balanced protection in an intergovernmental manner.⁷ Misappropriation or biopiracy is termed to have taken place when the sovereign right over natural resources of the state within their jurisdiction is patented without the sovereign's consent.

The vulnerability to exploitation is still prevalent despite the stipulations of a large number of international conventions and their deliberations. The agreement with TRIPS was a deadlock to the biopiracy. This situation was worsened later. The motive behind biopiracy is the inability to fulfil or actually meet patentability criteria. The prior art does not completely cater to the patent granting criteria. Added to that, natural resources are complicated to be improvised upon and patenting proceedings to it are also tedious in terms of its eligibility attainment and getting through the same. The monopolisation of GRs by corporations is the emergent spiral action towards its unruly application. The monopolisation of GRs by corporations is said to have been the emergent spiral action towards its unruly application.

The factors affecting the development of IP regime are numerous. The way people live in distress in bio-rich areas, a major calling for the creation of new intellectual property rights, so that long-term occupant communities can control plant genetic resources and protect their knowledge of the properties and characteristics of these resources was held primarily essential to devise protection mechanisms.

All researches are built upon skepticism and finding the way out to pave solutions to the actual problem is challenging. The very aspect of long-term occupants getting affected through new intellectual property rights claims is visible and catches the attention in terms of IP regulation and curbing biopiracy of genetic resources. These occupants do possess a considerable knowledge of the prevalent genetic resources and the biodiversity conservation techniques due to their accustomed behaviour and dependency on these resources. Irony lies in empowering these 'disempowered' people with their habitation, who actually possess a strong and critical knowledge base of the genetic resources. The aimed empowerment isn't possible through new

⁷ Vol 21, Divyangana Dhankar, *Commercialisation and Biopiracy of Genetic Resources in the 21st Century: The imminent need for stronger regulation*, Journal of IPR, NDLI, (2016)

IP rights as they disseminate and scatter these knowledge bases and consequently pave way to concentrating such resources into fewer hands who rarely possess such a knowledge. These automatically leads to biopiracy.⁸

For indigenous people, biopiracy is the most offensive and dangerous form of expropriation because it touches on the very core processes of life and survival. Worldwide, many indigenous and aboriginal communities are still active in holistic, renewing relationships reproducing and sustain- ing life. They see biodiversity as priceless and therefore as nonnegotiable. Biodiversity is their source of medicine, their source of food, and, critically, the source of their myths and customs. Selling their biodiversity is comparable to selling their culture and, more deeply, their souls — a kind of suicide. The epistemologies of indigenous cultures see biodiversity as a relational category that is ecologically and culturally embedded. For centuries local and indigenous communities, particularly women, have worked as caretakers of nature and keepers of its uses. Indigenous people’s knowledge comes from the plants themselves, from visions, from dreams, and from sacred beings. Knowledge is believed to be directly communicated from the landscape and is passed down orally through generations. It encompasses a fabric of nature that cannot be reduced to the assembly of bits of accumulated information. Indigenous peoples’ subsistence livelihood is based in knowledge of how to read the land, the plants, and the animals. As biological diversity is the material base for human life, biopiracy is an attack on people’s means of survival.⁹ This ecofeminist perspective on biopiracy in the Latin America settles down on its primordial concerns and lays down crystal clear notions and thought lines.

BIOPIRACY - GLOBAL PATENT POLICIES

Patent system reflects a 'carefully crafted bargain' that encourages innovation and promotes increased knowledge by providing an incentive to risk time, research, and development costs. It provides exclusivity that may result in a commercial advantage in the marketplace. The right to exclude is bound not only by territorial restrictions, but also by the legal parameters of patents. In particular, a patent allows exclusion of others only from the 'claimed invention' but not from all related subject matter. Claims are the technical 'metes and bounds' that describe the legally enforceable boundaries of a patent against other holders. Biopiracy allegations arise from patents that are based on, or in fact are identical to already existent genetic resources.

⁸ Paul J. Heald, *The Rhetoric of Biopiracy*, 11 *CARDOZO J. INT'L & COMP. L.* 519, Heinonline (2003)

⁹ Ana Isla, *An Ecofeminist Perspective on Biopiracy in Latin America*, Vol. 32, No. 2, pp. 323-332, The University of Chicago Press, Jstor (2007)

These allegations also arise based upon or identical to, traditional knowledge, such that it appears that the 'new' requirement has been violated.¹⁰

BIO-COLONIALISM - TRIPS' SAY

European colonialism, American occupation and the current intellectual property regime is applied to the patenting of genetic resources and the biodiversity. Both colonial doctrines and the international intellectual property rights regime arbitrarily render traditional knowledge and the traditional communities invisible or not within their purview, and leave them unprotected from appropriation by capital intense technologically developed economies. The genetics 'no man's land' is widely used and is a prevalent concept used of late and even before that since the evolution of genetics and patenting of genetic materials for the purposes of research. Today's international intellectual property rights regimes two key components: the TRIPS agreements and the national patent law of developed countries, primarily the US law. Knowledge and technology used by developing nations and indigenous cultures are invisible to the intellectual property law that allows for the allocation of value to natural and human resources. The current patent regime is in the process of recreating a colonial system, understood in its most basic form as the systematic extraction of the resources of one population by another. TRIPS has not only broadened the scope for patenting, including patenting of life forms, but also threatened, not literally, but in a haste to improvise on the exploitation of available traditional knowledge and resources and thereby to appropriate and not acknowledge contributions of indigenous communities. There is an asymmetrical economic and legal relationship between communities in the global South and corporates in the global North mediated by a series of institutions, including the states, with their own agendas. The promise of the patenting system is spurring the race for collecting bio-resources and knowledge through bioprospecting agreements. As databases of plants used by indigenous communities are established, biological parks are created to isolate and hide away regions rich in genetic resources and profits are disproportionately distributed, bioprospecting agreements appear to have heralded a new kind of dispossession.¹¹

¹⁰ Alejandro Madrazo, *Biocolonialism: TRIPs and the Genetic No Man's Land*, 25 GEO. INT'L ENVTL. L. REV. 487, Heinonine (2013)

¹¹ Das Kaushiki, *The Global Quest for Green Gold: Implications of bioprospecting and Patenting Indigenous Bio-resources and Knowledge*, Centre for the Study of Social Systems, Jawaharlal Nehru University (JNU), Jgate (2020)

BIOPIRACY OF GRs - RISK MANAGEMENT, CONCENTRATION OF RESOURCES AND DISCLOSURE - THREE-TIER STRUCTURE'S SAY

The last 3 decades were also marked by a height with intense of injustice felt by developing countries in the view to a phenomenon known as bioprospecting or biopiracy. Many highly successful biotechnology and pharmaceutical inventions by companies from northern countries were derived from plant genetic materials taken from less developed and developing countries. These companies had been given liberal access to these genetic resources, and often had exploited the traditional knowledge of indigenous people and cultural groups about how to use such resources, generally without charge, by basically extracting their critical knowledge. Many of the resulting inventions were patented, and in some cases the patent holders earned substantial profits through manipulation. Although the inventions and the subsequent profits would have been impossible without the raw material obtained from the developing countries, none of the profits were returned to the country from which the material was taken. There wasn't a trace of gratitude to credits. As ironical and to one's dismay it seems, indeed, people in developing countries from which the raw material originated had to pay the same prices as everyone else, and in some cases were not even given the access to the inventions derived from their indigenous material. Many developing countries came to view these practices to be an utter robbery or piracy in which wealthy multinational companies misappropriated the value of important natural resources of indigenous nature. This is all the more against IP rights to the original owner and exploitative of one's brainchild.¹²

It is very saturating to quantify the regularity and impacts of incidents that might be described as biopiracy of GRs. Applying intellectual property rights to plant material has been highly controversial in many countries. Many cultural and moral objections have been raised against the notion of owning life species. In addition to it, many people fear that the expansion of intellectual property rights could restrict traditional uses of plants and other substances found in nature. Although intellectual property rights are not supposed to allow materials to be taken out of the public domain once they have arrived there, several highly publicised, controversial cases have caused some observers to question whether this principle actually works when put into practice.¹³

¹² Shawn N. Sullivan, *Plant Genetic Resources and the Law. Past, Present, and Future*, Vol. 135, No. 1 (2004), pp. 10-15, American Society of Plant Biologists (ASPB), Jstor (2004)

¹³ Ibid

The combined rules and mechanisms of the Nagoya Protocol and the CBD propositions has fallen short on at least one front — the section on monitoring the access to benefit sharing from utilising the genetic resources, which is sandwiched within the compliance pointers. The typological proses in order to elaborate on biopiracy and its manifestation is indeed based on political leverage and commercialisation of researches to undermine the accrual of benefits to the actual needy. The business behind such activities do exist. Along with the biopiracy discourse has come lobbying for additional rights, particularly for indigenous people, including ideas for sui generis or solitary IP rights which ought to compete with an already competitive suite of private commercial rights that have come to be described as intellectual property, ironically. Indigenous customary laws foresee restoration of the cultural rights unto the people itself and the larger part of CBD's propositions are influenced by the bio-cultural rights accrual to the deemed ones. While there are misconceptions or areas which need more detailing or deliberation with regard to misappropriation and its relation to biopiracy as to mitigate grievances arising out of typologies of biopiracy and the solutions to it.

Thus, types widely sum up to the following:

Patent-based Biopiracy

The patenting, often apparently valid but not actually valid, inventions based on biological resources either involving or non-involving aspects of traditional knowledge that are extracted without adequate authorisation and benefit sharing from other countries usually being the developing countries, indigenous or local communities, is the patent-based biopiracy.

Non-patent Biopiracy

Other IP control, through plant variety protection or deceptive trade marks, based on biological resources and traditional knowledge that have been extracted without adequate authorisation and benefit sharing from other countries, indigenous or local communities, is termed to be non-patent biopiracy.

Misappropriations

The unauthorised extraction of biological resources or traditional knowledge for research and development purposes from other countries with jurisdictional rights over the resources

purported to be used in such researches, indigenous or local communities, without adequate benefit sharing.¹⁴

In summary, this typology of biopiracy and misappropriation accords with the Nagoya Protocol. But the Protocol is silent on IP — a considerable problem for policy-makers and those confronting IP-related biopiracy cases.¹⁵

Potential areas of synergy in the current procedural and disclosure related shortcomings in the patenting of genetic resources for carefully and systematically thought of purposes is lacking. A Matildic approach to seeing things of the subject matter which has come for the grant has to be developed in order to solder the holes. Protecting indigenous knowledge and customary ideals against biopiracy is to be watched with persistent care and conscious efforts. The ethnobotany underlying claims to restore jurisdictional rights in the indigenous people is valid enough to bring about the requisite alterations in the functioning of WIPO, TRIPS, CBD and the Nagoya Protocol and their say on biopiracy of genetic resources.

While the CBD, whose one of the most radical philosophical features was that it assigns use and control over biodiversity to individual countries, has imposed an obligation seek prior informed consent for the use of any sort of TK (Traditional Knowledge) as well s ensure benefit sharing, the system and regime of IPR has little requirement for benefit sharing. This leads to lack of knowledge amongst inspectors of patent applications, due to this inaccessibility. This directly facilitates biopiracy, since patents are blind granted for innovations based on the already prevailing knowledge with enough validations already.¹⁶

No consensus has been reached with respect to whether the disclosure requirement should be voluntary mandatory, or regarding the legal consequences of failure to comply with such requirement.¹⁷ The burgeoning bio-economy has witnessed various cases of biopiracy and its furtherance in the control aspects of it are being diverted Enroute middle men exploitation of the bio or genetic resources. The allegation of biopiracy to challenge bio based economic original projects to see diminishing results in its say. The way the bio-economy and the IPR

¹⁴ Daniel F. Robinson, *Biopiracy and the Innovations of Indigenous Peoples and Local Communities*, ANU Press, Jstor

¹⁵ Ibid

¹⁶ Hoang L, *Traditional Knowledge Documentation: Preventing or Promoting Biopiracy*, Journal of Tropical Agricultural Science, J-Gate

¹⁷ Hamdallah Zedan, *Patents and Biopiracy: The Search for Appropriate Policy and Legal Responses*, Vol. 12, No. 1, pp. 189-205, Brown Journal of World Affairs, Jstor (2005)

regime treat nature, culture, knowledge, and the interlinkages are subject to critiques and the study is stupendous in its mitigation aspects. Biopiracy is also affecting feminists in a very unique way.

HUMAN GENETICS AND FUTURE ENDEAVOURS' PREDICTION

Probably the most important immediate issues concerning the new technologies revolve around their ability to predict future expressed characteristics. The strength of the link between the human gene sequence, or genotype, and the functioning person, or phenotype, is often exaggerated, but in some cases genotype does determine phenotype and in other cases strongly influences it. Genetic tests look for genotypes that help predict phenotypes. To the extent that such tests allow medical interventions that benefit the tested person, they are rarely controversial. But the predictions from genetic tests can be problematic in at least four respects: (a) through parental decisions about childbearing, (b) through individual and familial reactions to prediction, (c) through private third-party discrimination based on the predictive information, and (d) through government action. Many of these effects could take place as a result of research on either individual or population genetics.¹⁸ So, these researches are a way out to determining the scope of researches and their possible extent to which the use of genetic resources implying a key role in identifying the particular study's inference and future endeavours based on such planned researches with reliant deductions. Although the rules for the new science are not yet fixed, building on the preceding discussion, we find some areas of consensus. First, privacy is too large an issue to be solely the responsibility of geneticists, or any other group. The involvement of ethicists, social scientists, lawyers, and representatives of affected communities in appropriate cases is an important protection against the errors of judgment that may result from narrowness of perspective. Rather than regarding this sort of consultation as a threat to their projects, scientists should embrace the opportunity to broaden their consideration of public concerns and to educate the public concerning their work.¹⁹

PRIVACY AND CONFIDENTIALITY OF GENETIC INFORMATION - RULES

Although there may be debate concerning the contours of the sphere of privacy necessary for autonomy, the erosion of privacy should never be watched with complacency. The researchers

¹⁸ Henry T. Greely, *LEGAL, ETHICAL, AND SOCIAL ISSUES IN HUMAN GENOME RESEARCH*, Annu. Rev. Anthropol. (1998)

¹⁹ Mary R. Anderlik and Mark A. Rothstein, *PRIVACY AND CONFIDENTIALITY OF GENETIC INFORMATION: What Rules for the New Science?*, Annu. Rev. Genomics Hum. Genet. (2001)

involved in any notorious experiment aren't wholly monsters. This misconception is due to the extraneous processes and complexity in the research information. However, the researchers believe they were accruing benefits to the society. Their error lay in disregarding the intrinsic harm of enlisting human beings and sacrosanct genetic resources in research without the respective consent and treating individuals as mere means to scientific ends. Since, genetic information is connected to personal and group identity, protecting the privacy of genetic information is an important individual and social priority. Genetic privacy has intrinsic value as a facet of autonomy, and respect for autonomy implies a duty to respect the genetic privacy of others. Within a legal framework, genetic privacy must be considered a fundamental right, and individuals should be able to block or seek redress for invasions of their genetic privacy by other people and by the government. Rules protecting the privacy of genetic information are intended to prevent, lessen, or eliminate negative consequences of the new genetics. Even if one accepts that privacy is a fundamental value, it does not follow that privacy is an absolute value. Some controversies that are likely to arise in genetic research concern with the nature and value of consent, including the acceptability of research without consent or of blanket consents to future research; the appropriate role of community representatives in research; and the desirability of commercialisation with or without benefit sharing. In each case, the debate is less about consequences than it is about the meaning of respect for autonomy and about fundamental human rights. although laws protecting the privacy of health information and prohibiting genetic discrimination are in place in most jurisdictions, there are gaps in these laws and in the social safety net.²⁰ Scientists, and others involved in the enterprise of genetics, can improve the situation by engaging in vigorous advocacy for enhanced legal protections and by conscientiously adhering to guidelines contained in consensus documents, whether or not implemented as a matter of law.²¹

RESISTANCE TO BIOPIRACY

Biopiracy holds a threat to indigenous people who depend on biodiversity for survival, through their expertise on GRs. The mobilisation to confront biopiracy due to the corporation and its activities to procure IP rights with undue influence unto the officials, is witnessing an uphill now. The concept of 'biodiversity belongs to the commons' urges every single individual to protest and regain their rights over common usage and protection. Hence, it is clear that nobody

²⁰ Ibid

²¹ Supra Note 19

can misappropriate or seek ownership over that which belongs to the community. This notion is prevalent and increase the growth index of indigenous people and also foresee future prospects to business industries, which it is possible to obtain a patent only thorough proper and requisite authenticity in their research.²²

REGIONAL AND INTERNATIONAL INITIATIVES TO COMBAT BIOPIRACY

The issue of biopiracy of genetic resources is foreseen to be resolved through a detailed search for appropriate legal framework responses. Sharing patent benefits with the countries that provide genetic resources offers an incentive for biodiversity conservation. It guarantees effective participation and involvement of crucial actors at the local level in conservation and sustainable use activities. More significantly, for those pursuing research and development, continued access to genetic resources and traditional knowledge is critically linked to effective benefit sharing arrangements. It is therefore in the interest of provider countries, user countries, and relevant stakeholders that measures are put in place at national and international levels to promote transparent, fair, and equitable access and benefit sharing arrangements.²³ For sure, a number of IPR instruments and measures at national and international levels consider IPR in the eye of benefit sharing through royalties to the destined and the true owner of the knowledge.

BATTLING BIOPIRACY

In the global fight against biopiracy, one of the key issues is to prevent the grant and exploitation of patents on traditional knowledge and genetic resources by requiring that patent applicants for inventions involving traditional knowledge and genetic resources disclose the source of those resources and provide evidence that the prior informed consent of the local owners of such resources has been obtained and that benefit sharing agreements have been entered into with those owners only. The obligation to disclose the use of traditional knowledge and genetic resources in an invention beyond the sanctions are attached in case of violation of such obligations at the international level. This centralises the objectives to ensure the effective sharing of benefits resulting from the use of such resources with the local communities that own them, and to implement appropriate mechanisms for the purpose of affirming equitable

²² Supra note 8

²³ Supra note 14

benefit sharing.²⁴

Considering the 'Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising from their Utilisation' adopted by the CBD, is a useful first step in an evolutionary process for the development of access and benefit sharing regimes. The act of establishing a mechanism for cooperation and exchange of information regarding property rights of genetic resources amongst diverse countries is helpful to successfully enforce law and its regulations and thereby reduce duplication of works and granting new patents to the same old inventions using the genetic resources.²⁵ At the last three meetings of the U.N. Convention on Biological Diversity, civil society and Indigenous people's organisations hosted the 'Captain Hook Awards' ceremony to highlight the most egregious cases of biopiracy, and to demonstrate that the CBD has to pull up its socks to do something to battle it over and stop it. Patent regimes require urgent societal review, and that property 'rights' must not be allowed to trample human rights. The U.N. Human Rights Commission has identified intellectual property as an obstacle to the rights of poor people in the global South. As it seems, IP is to be brought to the remotest accesses in order to effectuate the fruits and benefits to be experienced by the first and the last man on earth. Ultimately, the most important way to stop biopiracy is to strengthen and protect the control of local communities over the biodiversity they nurture, and to resist legal systems, international treaties or contract agreements that seek to privatise the people's rights and also the rich biodiversity.²⁶

The plan of action to quantify, qualify and categorise existing concerns of the indigenous communities and their say on genetic resources and its privatisation demon's notions and the resultant biopiracy was developed to combat against biopiracy. Some scholars suggest that the mandatory disclosure of origins requirement and prior informed consent should become additional conditions for patentability requisites. The disclosure of origins requirement would compel bioprospectors to include information about the origin of the genetic resource and the source of the traditional knowledge in their patent applications.

²⁴ Jacques de Werra, *Fighting against Biopiracy: Does the Obligation to Disclose in Patent Applications Truly Help*, 42 VAND. J. Transnat'l L. 143, Heinonline (2009)

²⁵ *CUSCO DECLARATION: ON ACCESS TO GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND INTELLECTUAL PROPERTY RIGHTS OF LIKE-MINDED MEGADIVERSE COUNTRIES*, Australian Indigenous Law Reporter (AILR), Vol. 8, No. 2, pp. 101-103, Indigenous Law Centre, Law School, University of New South Wales, Jstor (2003)

²⁶ Hope Shand, *Predatory Patents: Biopiracy and the privatisation of global resources*, Vol. 11, No. 1, pp. 35-36, Reimagine!, Jstor (2004)

CORRECTIONAL MECHANISMS - APPROACH AND PROCESSES

Patent monopolies show negative impact on the global community. Some countries have managed to fight biopiracy through the legal re-examination processes devised after time tested deliberations. Despite some success, this method has actually proven to be both cumbersome and expensive. There have been significant cases of how unjust patents can still create financial benefits to the patent holder, i.e., yearly profits and royalties for patent holders as a function of overly complicated and grindingly bureaucratic re-examination processes, which necessitate the rigidity to be brought into such devised processes, mechanisms to prevent biopiracy and protect genetic resources. Developing countries ought to focus on these actions to detect misappropriations and push and vouch for the establishment of expedited procedures to re-examine patents and find unjust patent holders liable for illegally gained profits. It is likely to be deciphered that as countries become more experienced in detecting TK based infringements, they would eventually also develop internal mechanisms to more efficiently handle and correct biopiracy through their re-examination processes.²⁷

THINKING GLOBALLY AND ACTING LOCALLY - FROM COMMON HERITAGE TO EQUITABLE BENEFIT SHARING

The 1983 International Undertaking mentioned that it was based on the universally accepted principle that 'plant genetic resources are a heritage of mankind and consequently should be available without restriction' that illustrates the development in global thinking over the past two decades about how best to preserve genetic and cultural diversity, while simultaneously fulfilling the goal of promoting economic development. While, this was subject to interpretation in different ways pervasively. By 1989, however, a resolution of the FAO (Food and Agriculture Organisation), entitled 'Agreed Interpretation of the International Undertaking' included and recognised that some countries had not adhered to the Undertaking or had adhered with reservation because of possible conflict with their obligations under the UPOV (International Union for the Protection of New Varieties of Plants), while other countries had not adhered or adhered with reservation due to conflicts with the existing national regulations. This triggered a fear of undercutting the recognition IP rights of right holders. The new International Treaty on Plant Genetic Resources for Food and Agriculture abandons the phrasal usage of 'common heritage of mankind' altogether. Instead, it states that the objectives

²⁷ Lorna Dwyer, *Biopiracy, Trade, and Sustainable Development*, 19 COLO. J. INT'L ENVTL. L. & POL'y 219, Heinonline (2008)

of the Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and also ensuring food security. The Treaty spells out the obligations of its member countries to promote the exploration, conservation and sustainable use of plant genetic resources. Certain contractual agreements for access to genetic resources and benefit sharing govern the transfer of genetic materials for a variety of purposes, including ex-situ conservation in gene banks, research and development, commercial exploitation, or a combination thereof, and have become collectively known as MTAs (Material Transfer Agreements). The WIPO declarations on Intellectual Property clauses of contractual agreements concerning the access to genetic resources and benefit sharing describes essential categories of public policy frameworks which are relevant to contractual agreements for access and benefit sharing of the generic resources. It thus, provides a sampling of contractual provisions governing the scope of the contract, the respective intellectual property rights and obligations of the provider and recipient of genetic materials, and other standard clauses governing such matters as dispute resolving mechanisms, the term and termination of the contract, entry into force, and cancellation. These aspects looked after thereinto guide contractual clauses. These global thoughts through treaties and mechanisms, were put into implementation to reap actual results. How the foregoing global thinking can be acted upon locally was found in the ICBG (International Cooperative Biodiversity Groups) programme. Proposals were required to address each of the objectives of growth, protection and sustainability, to include substantial and novel efforts in natural products drug discovery, biological inventory, research capacity building, and benefit sharing, and to include at least one associate program within each ICBG project based in and led by a developing country organisation. This way, the local level implementation flourished. The goal of bioprospecting contributing to conservation and economic development was proven through the ICBG programme. In any event, valuing traditional knowledge and bioprospecting wholly, by the extent to which they lead directly to the development of commercially viable products may be employing an inadequate metric. As the organisers of the ICBG program emphatically note, drug discovery is a high risk prone science, and biodiversity prospecting is essentially a research tool and helps in succeeding the best when treated the way it ought to be.²⁸

²⁸ Charles R. McManis, *Intellectual Property, Genetic Resources and Traditional Knowledge Protection: Thinking Globally, Acting Locally*, 11 CARDOZO J. INT'L & COMP. L. 547, Heinonline (2003)

Meanwhile, prior informed consent would require bioprospectors to show proof of obtaining prior informed consent from the GR-holders before being granted a patent. Although some national legislations have incorporated requirements for disclosure of origins and prior informed consent, an international system mandating these two additional conditions for patentability does not currently exist. The harmonisation of TRIPS and WTO agreements and principles was then necessitated. Sui generis system of IPR, wherein a distance legal system creation can be possible, and private agreements, wherein it enables the bioprospectors to own, use and license the genetic resources, through a fair arrangement between the GR-holders and bioprospectors, are surely positive protection mechanisms against biopiracy. One potential method to address the injustice and unfairness of biopiracy may be found by creating a legal regime that provides GR-holders with mandatory control and permissive equitable benefit-sharing while simultaneously ensuring that bioprospectors have access to genetic resources. One prospective goal to expand bio resources usage and curb biopiracy is to arrive at a concessional agreement through a private arrangement.²⁹ In reality, there is no international consensus on the substance of the internationally acceptable regime of protection. This is to be expected, as the countries having the resources in the form of genetic resources, traditional knowledge and folklore would try to secure protection for such resources, and the user countries would be reluctant to subject themselves to any additional restraints to their producing of innovations and creativity in line with the existing intellectual property agreements. This notion is bit unclear. However, such perceived resistance may not be long-lasting once a clearer form and substance of the internationally acceptable regime hopefully emerges. Besides, the user countries are at the same time the holders of genetic resources, traditional knowledge, and folklore and vice versa.³⁰

On a lighter note, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) is an ambitious document. It seeks to vindicate the interests of parties that previously were underrepresented in international legal policy relating to plant genetic resources. At the same time, it seeks to assure industrial users of such resources that their economic interests will not be harmed. And, of course, the overriding objectives of the Treaty are the conservation and diversification of PGRFA and the reinvigoration of international

²⁹ Tak Jong Kim, *Expanding the Arsenal against Biopiracy: Application of the Concession Agreement Framework to Prevent Misappropriation of Biodiversity*, 14 SMU Sci. & Tech. L. Rev. 69, Heinonline (2011)

³⁰ Weerawit Weeraworawit, *Formulating an International Legal Protection for Genetic Resources, Traditional Knowledge and Folklore: Challenges for the Intellectual Property System*, 11 CARDOZO J. INT'L & COMP. L. 769, Heinonline (2003)

exchanges of germplasm. Although the Treaty is more specific in some respects than the CBD, its policies are stated broadly, and often without significant practical detail. For these and other reasons, the Treaty can be thought of as a platform on which the detailed structure of an international policy for plant genetic resources can be built. What that structure will look like when it is completed will depend upon a variety of political, economic, and scientific influences that are already at work to shape the policies of the future.³¹

INDIGENOUS SELF DETERMINATION IN THE ERA OF GENETIC PATENTING - EMERGING HUMAN RIGHTS

Genes and the information they contain are fundamental building blocks of a people's identity. Genetic research on groups of people occasionally results in lucrative biotechnology patents. There are many competing interests in the arena of sampling and patenting of indigenous peoples' genetic material. Genetic research has the potential to yield diagnostic tools and cures for diseases, and many people suffering from or predisposed to these diseases stand to benefit from this. Other potential beneficiaries include scientists, pharmaceutical companies, and the larger health industry, all of which could profit from a successful patented product. In addition, anthropologists, geneticists, and indigenous people could learn more about the migratory history of indigenous tribes through genetic research. This detail mentions the beneficiaries and uses of genetic research. Apart from these potential benefits, indigenous people have primacy concerns about the procurement and use of their genetic materials, especially worried about researchers obtaining genetic samples without the informed consent of their subjects. Some of these people's religious or philosophic beliefs do not permit the patenting of life. No avenues exist for these people to enjoin the patenting of their genetic material. No mechanisms beyond private contract currently ensure that the indigenous donors will be adequately compensated, or compensated at all, for their contribution. Moreover, many indigenous people may never have access to medical advances based on their own genetic material because they do not live near medical facilities. Currently, a controversy rages over the patenting of genetic information. The need to self actualise amongst the regional people over powers the need to promulgate or protrude broad thinking permits due to the deprivation of their own genetic materials information and their disclosure. Sometimes it is less challenging to pay nominal homage to current formulations of human rights to recast them to fit the modern variations of

³¹ Sullivan, S. N. 'Plant Genetic Resources and the Law: Past, Present, and Future', <https://doi.org/10.1104/pp.104.042572>, accessed on 25th September 2022.

traditional violations. The current conceptualisation of human rights must develop because it does not adequately protect indigenous people who are frequently harmed in the process of modernisation. Although it is negligibly important to identify the basis for enhanced protection to legitimise a right, finding equitable solutions that make a difference in people's lives must be the goal. That difference can be made by protecting the rights of indigenous people while helping to keep responsible and fair genetic research viable.³²

CONCLUSION AND SUGGESTIONS

It is the inherent unfairness of the IP regime that has caused the north of biopiracy from the procurement of south side traditional knowledge. Even if the South is allowed to have some kind of intellectual property rights over their genetic resources, for instance through legislation patterned after the Model Provisions or through the Traditional Knowledge Registries, such legal solutions would be contrary to traditional ownership patterns.³³ Biopiracy has happened to be the most impacting, on the biodiversity, more significantly in a privative way. The nature and people ought to exist in harmony and balance in order to coexist. This phenomenal mark on the balance idealised to be maintained is the aim of affirmation. Researchers or research organisations take biological resources without official authorisation, largely from less affluent countries or marginalised people.³⁴ This way, the patenting crowds up and biopiracy reaches its peak when time management and piled up work need to be managed simultaneously. Biopiracy largely affects countries dependent on agriculture for its growth. Indigenous GRs are patented for profits by large corporates and individuals who engage in scandals and seek to reap benefits out of greed. Such agriculturally dependent people would be unfairly affected by unauthorised patenting in the name of research. The deal can be consented based on consensus to compensatory remedies and payments to the worst hit or the actually hit. Regulatory laws to streamline and implement proper compensatory attitudes in people towards the indigenous people must be fostered, because innocents can not be put at stake for inappropriate concentration of resources or commercial exploitation of resources that aren't exclusive to only the companies or greedy individuals. The impact on culture, biodiversity and the resources to get replenished by themselves by giving them the proper

³² Kara H. Ching, *Indigenous Self-Determination in an Age of Genetic Patenting: Recognising an Emerging Human Rights Norm*, 66 *FORDHAM L. REV.* 687, Heinonline (1997)

³³ Remigius N. Nwabueze, *Ethnopharmacology, Patents and the Politics of Plants' Genetic Resources*, 11 *CARDOZO J. INT'L & COMP. L.* 585, Heinonline (2003)

³⁴ Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 *U. MICH. J.L. REFORM* 433 (2006)

breathing time is to be given the proper attention. Financial and emotional needs are bent upon their survival source, I.e., the nature and its products usable by men. The patents held by other countries for turmeric, basmati rice and need, to mention a few is a clear cut example to biopiracy. Procedural and human carelessness in letting go of it to the other countries is the ethical point of view to this issue. Due to the patenting of biological materials, or genetic resources, the locals of the affected countries have less, so to say, none at all, access to those new developments which is possibly their original idea or discovery at the first place. Hence, the quest for justice cannot be undermined or denied. Problematic areas need to be mitigated to restore peace and not created a new to hog the limelight to gain a short-lived reputation amongst various other people. A consideration of socio cultural conflicts to arise join the future is enough motivation to look for and address global patent policies to cur biopiracy. Intellectual Property issues are often overlooked for its lifestyle thinking which is actually the essence of Prithvi and human beings and the concept of coexistence. Which is the re woven reason why policies are to be altered and adulterated policies are to be stripped away. Patent imperialism can not overtake genuine resources' stake held by indigenous people. This add on to the society in terms of its equality maintenance is though to be perceived in an orderly manner and proposals on fallacy of patent seeking giants are not be entertained so that reconsidering the uniform tenet of patent laws can be set and put forth. What started as a concept or rationale for inclusion of IP into a global trade agreement, must not be subject to wraths and undue influences in procuring patent exclusives and that too t the cost of indigenous innocents.

The foregoing analysis underscores the delicate intersections between intellectual property rights, genetic resources, and traditional biodiversity-related knowledge. Those intersections raise complex legal and policy issues relating to conservation, sustainability, ownership, governance, and equity. The international intellectual property rights regime will require to accommodate legitimate concerns relating to access to and utilisation of genetic resources and the related traditional knowledge.³⁵ International responses through careful discussions and deliberations must achieve a realistic balance between facilitating access to genetic resources and traditional knowledge for the purposes of research and development, promoting the conservation and sustainable-use efforts of provider countries and communities, and harnessing and sharing the benefits so derived from commercialisation in an equitable manner. Developments at regional and national levels contain crucial lessons regarding the direction or

³⁵ Supra note 16

the course of desired change and should inform policy choices at a pervasive level so as to affirm at its best efforts to curb biopiracy and give back from where it originated, i.e., what came from the traditional groups itself to be returned to them with whole hearted credits and just royalties.

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