

INTERNATIONAL JOURNAL OF LAW
MANAGEMENT & HUMANITIES

[ISSN 2581-5369]

Volume 5 | Issue 1

2022

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The Issue of Biopiracy & Protection of Traditional Knowledge

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ABSTRACT

Protection of Traditional Knowledge (TK) is important to the one who owns them as it is created and brings economic stability to the one who owns them, which to create a sphere that such kind of knowledge should not be destroyed or eroded. But the reason behind the bestowed that TK is being misused is because there is a lack of identification and documentation as a mechanism that is designed to be protective of the TK. The reason for not having a proper mechanism that gives multinational companies to use and exploit such kind of knowledge for the purposed of their commercial benefits by obtaining them for patenting System. The absence of the proper data-based has been the major issue for the protection of TK, especially in today's world, and one of the major issues is that of Bio-Piracy. It is important to highlight the compulsions traditional societies face to safeguard their knowledge based on unauthorised exploitation by third parties. In this paper, an attempt has been made to understand how the Bio-Piracy is affecting the Traditional Knowledge bearers of India, further what steps have been taken by the authorities to address the issue and how far they have been successful in the same. Lastly, in this paper, recommendations and suggestions towards the prevention of Bio-Piracy and protection of traditional knowledge have been made.

Keywords: *Bio-Piracy, Traditional Knowledge, TRIPS Agreement, India's biological diversity act, 2002, Traditional Knowledge Digital Library,*

I. INTRODUCTION

The frequent advancement of science and technology has made knowledge a valuable commodity, and because of the increased importance of knowledge, intellectual property concerns have also increased in comparison to the previous era. Development and progress have resulted in detrimental side effects, and biopiracy is one such side effect. Biopiracy is the unauthorised or uncompensated use of biological resources and traditional knowledge that belongs to other countries and to their local and indigenous communities that are mostly developing. Genetic resources and traditional knowledge associated with these resources today

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play an important role in various sectors of society and industry, mostly plants and animals, food and beverages, horticulture, and industrial biotechnology³.

II. DEFINING BIO PRIVACY

Biopiracy is a phenomenon that has started to get international attention recently. Concerning the concept of bio-piracy, there is no official definition. The term is relatively new and was first used in the early 1990s and is closely related to the term bioprospecting, also used during the same period. The term bioprospecting is defined in the Oxford Dictionary as “*the search for plant and animal species from which medicinal drugs and other commercially valuable compounds can be obtained*”⁴. Biopiracy is a discursive tool that both describes an injustice and is used for political leverage. “Although the colonial enterprise of plant and animal collection has been going on for centuries, the biopiracy discourse has emerged as a powerful counter to the perception of new hegemonies imposed by IP rule with global reaches, such as the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).”⁵

Along with biopiracy, the discourse has come lobbying for additional rights, particularly for indigenous peoples, including ideas for sui generis IP rights which must compete with an already competitive suite of private commercial rights that have come to be described as ‘intellectual property’. Lobbying for additional third-generation rights, which we might call ‘bio-cultural’ rights of indigenous and local peoples, has been comparatively more successful in forums such as the CBD, where we now see the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) influencing the text of the Nagoya Protocol towards recognition of indigenous customary laws (Article 12).

These developments and associated lobbying are deliberately targeted towards the issue of biopiracy, even if international forums are unable to address that issue directly. For example, in the absence of a definition of biopiracy, international organisations are left without an appropriate term to describe the specific or perceived injustices. In this void, delegates to the various agreements such as the CBD or organisations such as the WTO commonly use the term. Given that the issue of biopiracy is highly controversial, it is no surprise that the terminology is being disputed equally. Biopiracy is often replaced as a derogatory term by

³ Kumar, Nithin V. "Protection of Traditional Knowledge: International and National Initiatives and Possible Ways Ahead." Available at SSRN 2012724 (2012).

⁴Kaur, Gunnjeet, Manvendra Singh, Manju Kumari Choudhary, and Ravindra Kumar. "Bio-prospecting: A Systematic Search." *Indianfarmer* 1202: 1142.

⁵ Bavikatte, Kabir, and Daniel F. Robinson. "Towards a people's history of the law: Biocultural jurisprudence and the Nagoya Protocol on access and benefit sharing." *Law Env't & Dev. J.* 7 (2011): 35.

terms such as unauthorised access and misappropriation. This is how definitions of these terms are increasingly entangled, yet each author defines them differently. A lot of critics say there's no such word or thing as biopiracy. The argument regarding this is that most corporate people are simply acting under existing international laws on property. It is also stated that the idea of sovereignty over natural resources and biodiversity not only gives rights to nations but also imposes certain obligations which sometimes countries forget. Consequently, governments should blame themselves for the failure to protect their biodiversity and for not placing limits on research and biological resource appropriation. Such arguments are very harsh towards developing countries, but some rational points are therefore deserving of special regard to consideration.⁶

Bio-piracy is not a term with accepted legal meaning, as discussed earlier. Different scholars, activists and lawmakers have given different meanings according to the requirements. The term biopiracy is defined in the Oxford Dictionary as *"the practice of commercially exploiting naturally occurring biotechnical or genetic material especially by obtaining patents that restrict its future use while failing to pay fair compensation to the community from which it originates."*⁷

(A) Issue of Bio-Piracy in India

Both medicinal plants and traditional knowledge are pre-existing with indigenous communities, tribes, or locals. Since there is no proper documentation, exclusive patent rights are granted to those parties that are not the TK's real owners. The conflict arises because of the trade interest, and the patent holders make profits, and they never disclose the knowledge to others. Moreover, the national and international conventions did not define the holders of medicinal plants, TK and patents. There are also no provisions for sustainable resource use and maximum amount of resource exploitation by the patentee. TK as novelty, non-obviousness and use for commercial advantages all of these must be recognised. Only the TK is not to be preserved, but it is necessary to recognise and preserve the biodiversity, resources, culture of the local people. There have been several cases of TK bio-piracy coming from India in the recent past.

Firstly, it was the patent on turmeric's wound-healing properties. In other countries, patents on the hypoglycemic properties of bitter melon, brinjal etc., have now been obtained. In this

⁶Dawyndt, Peter, Tom Dedeurwaerdere, and Jean Swings. "Exploring and exploiting microbiological commons: contributions of bioinformatics and intellectual property rights in sharing biological information. Introduction to the special issue on the microbiological commons." *International Social Science Journal* 188 (2006): 249-258.

⁷Biopiracy, Oxford Dictionaries, Oxford University Press, (Available at: <http://oxforddictionaries.com/definition/english/biopiracy>. Accessed on 05th February 2022)

context, an important criticism relates to foreigners getting patents based on Indian biological materials. There is also the view that the TRIPS Agreement helps biodiversity exploitation by privatising the biodiversity expressed in life forms and knowledge. Patents are granted following national patent law and only have territorial application. The TRIPS Agreement provides minimum standards for the protection of intellectual property rights, including patents, while WTO members are free under their national law to grant a higher level of protection. Thus, except for micro-organisms and microbiological and non-biological processes, India is free to deny patents in life forms, as provided for in the TRIPS Agreement. At the same time, if, for instance, the US opts to grant patents on plants or other forms of life, we cannot object. Such patents will, however, only have force in the US and cannot be enforced in India. To assess the compatibility of a patent granted by a foreign patent office with an invention based on biological material obtained from India, we need to check whether the patentability criteria, i.e. novelty, non-obviousness and utility, are met, and challenge it where the criteria are not met. We are looking into cases that need to be reviewed.⁸

Such revocation actions and domestic biodiversity legislation alone cannot solve the problem of bio-piracy. There is a need to provide adequate legal and institutional means for the international recognition of tribal communities' rights to their TK based on biological resources. Mechanisms for the sharing of benefits arising from the commercial exploitation of biological resources at the international level. Mechanisms for sharing benefits arising from commercial exploitation of biological resources using such TK also need to be instituted. This can be achieved by harmonising the various approaches of the Convention on Biological Diversity on the one hand and the TRIPS Agreement on the other since the former recognises the sovereign rights of States over their biological resources and the latter treats intellectual property as a private right.⁹

In this context, India proposed that patent applicants should be obliged to reveal the source of origin of the biological material used in their invention under the TRIPS Agreement and that prior informed consent of the country of origin should also be required. If this is done, it will allow for domestic institutional mechanisms to ensure that the patent holders share the benefits of such commercial use with the indigenous communities whose TK has been used. At the same time, provisions were introduced in the amendments proposed to the Patents Act 1970 through the Patents (Amendment) Act 2005 for disclosure of the source of biologic material.

⁸Source: WTO documents: WT/CTE/W/156 and IP/C/W/198

⁹Oli, Krishna Prasad. "Access and benefit sharing from biological resources and associated traditional knowledge in the HKH region-protecting community interests." *International Journal of Biodiversity and Conservation* 1, no. 5 (2009): 105-118.

What is required, apart from preventing bio-piracy, is the acceptance by all patent offices worldwide of this disclosure practice and PIC. Because of biodiversity, in rich countries like India, the protection of traditional knowledge has always been an issue of interest. Such knowledge has always been in the hands of the indigenous and local communities that are being exploited on a large scale without giving them a share of the profit. These resources are used in such a way as to result in bio-piracy. The unique nature of such knowledge makes it unfit for the existing legal structure for protection.¹⁰

As the social structure became complex, and the pattern of human settlement evolved from primarily tribal societies to complex and even more complex villages, the notion of THINE & MINE became more and more manifest in human life. The concept of private property was developed, spreading from tangible objects to intangible phenomena such as the intellect and ideas of knowledge. To this extension of the ownership, the scope was evidenced by the creation of the legal concept of Intellectual Property. Traditional knowledge is thus a major valuable asset for the local community on which their livelihood depends and a tool for better management of their local ecosystem.

Traditional knowledge is used as an input for modern industries such as pharmaceuticals, botanical medicines, cosmetics, modern wear, agriculture, biological pesticides etc. Protecting traditional knowledge thus has the potential to improve the performance of many developing countries' economies by making their biological wealth more commercially available and increasing exports of traditional knowledge-related products. Several academic studies on traditional communities provide ample evidence that traditional knowledge protection can bring significant environmental benefits.¹¹ Much of the world's crop diversity lies in the custody of farmers who follow age-old farming and land-use practices in ecologically complex farming systems that allow biodiversity conservation. Bio-piracy of codified traditional Indian knowledge continues, as this information is available in regional languages, and there is a language barrier that prevents patent offices from searching for this information as prior art before granting patents. Formulations from traditional knowledge used for the treatment of human ailments are time-tested since they have been in practice for centuries. The reliability of traditional medicine systems, coupled with the absence of such information with patent offices, provides interlopers with an easy opportunity to obtain patents on these traditional

¹⁰Sharma, Bhavika, Shalini Singh Maurya, and Jesmita Brahmacharimayum. "India's Fight Against Agricultural and Medicinal Plants' Biopiracy: Its Implications on Food Security, Traditional Rights and Knowledge Degradation." *International Journal of Agriculture, Environment and Biotechnology* 11, no. 6 (2018): 881-887.

¹¹Venkataraman, K., and S. SwarnaLatha. "Intellectual property rights, traditional knowledge and biodiversity of India." (2008).

medicine systems derived therapeutic formulations. The granting of patents on non-patentable knowledge relating to traditional medicinal products, which is either based on existing traditional knowledge of the developing world or a minor variation thereof, has caused the developing world great concern.¹²

Some of the examples for the bio-piracy of traditional knowledge are discussed herein, and in many of these cases, the country has had to fight for revocation of the patents granted. The revocation may not be a feasible option for all patents that have been taken on traditional knowledge, as it involves huge costs and time. In the international patent offices, while examining the patentability of any claimed subject matter, patent examiners use available resources to search the appropriate sources of non-patent literature.¹³ It was, therefore, necessary to create easier accessible non-patent literature databases on India's traditional knowledge.¹⁴

There are ethical, economic, scientific, and moral reasons for protecting traditional knowledge. For thousands of years or centuries, however, the question of preserving traditional knowledge never arose; it has become very significant today. Various attempts to obtain the protection of intellectual property on naturally occurring substances have alerted developing countries such as India to the value of traditional knowledge. These countries have only begun to realise the importance of traditional knowledge after the Western advanced scientific nations have begun to grant traditional knowledge rights of intellectual property in their nations. Such use can be called Bio Piracy, whereby unauthorised extraction of biological resources or traditional knowledge from developing countries is done to obtain patents without compensating the original holders of knowledge¹⁵. The patent is an exclusive right granted to the inventor by the government for the invention. Novelty, utility and inventiveness are the criteria for obtaining a patent. Novelty means that the invention must be completely new or original, which is not otherwise known. Utility refers to the practical use of any invention and its industrial application. Inventiveness means non-evidentness, meaning that the invention must be such that it is not evident and that it is advanced in technology compared to any person skilled in that technology. The patent holder may, after obtaining a patent on the invention, prevent

¹²Twarog, Sophia, and Promila Kapoor. Protecting and promoting traditional knowledge: systems, national experiences and international dimensions. UN, 2004.

¹³ Gupta, V. K. "Protecting Indian traditional knowledge from biopiracy." In International Conference on Utilization of the Traditional Knowledge Digital Library (TKDL) as a Model for Protection of Traditional Knowledge, New Delhi, India, March, vol. 22. 2011.

¹⁴Ibid

¹⁵Reddy, Prashant, and Malathi Lakshmikumaran. "Protecting Traditional Knowledge Related to Biological Resources: Is Scientific Research Going to Become More Bureaucratized?." Cold Spring Harbor perspectives in medicine 5, no. 10 (2015): a020974.

anyone from using or producing that invention.¹⁶

III. CASES STUDY OF LANDMARK BIO-PIRACY CONTROVERSIES

(A) Neem Case

The botanical name of the Neem Tree is *Azadirachta Indica*. The word is rooted in *Azad-Darakth*, the Persian language. The tree was described by Indians as *Azad Darakht-i-Hindil*, which means India's free tree. Neem trees are attractive tropical evergreens that can grow to a height of 30 meters and a girth of 2.5 meters. The neem tree that has been able to live for over two centuries is native to the Indian subcontinent. Over the past century, many countries in Africa, Central and South America, the Caribbean and Asia have flourished. The tree is listed in Indian texts written over 2000 years ago and has been used as an insect and pest repellent in agriculture, human and veterinary medicine, toiletries, and cosmetics for centuries. For medicinal purposes, every part of this tree, from its root to bark, leaves and seed, has been used. It has been used to cure diseases as well. The use of neem oil itself is lamps for lighting. It is also revered in the region's religions, culture, and literature. India has shared knowledge with the world community about its myriad uses. Neem cannot, on the one hand, be the subject of a patent simply because it is indigenous to the region of South Asia and part of its bio-knowledge, and therefore does not fulfil the criteria of novelty necessary for the grant of a patent. On the other hand, neem seeds and their potent insecticidal extract in the United States.¹⁷

Azadirachtin has been the subject of ongoing biotechnology research and patent grants. Consequently, the multinational agribusiness company WR was established on 12 December 1990. Based on a US priority application dated 26 December 1989, Grace of New York, and the United States of America, represented by its Secretary of Agriculture, filed a patent application with the European Patent Office (EPO) covering a method for the control of fungi on plants with the aid of hydrophobic neem oil extracted. Several patents were subsequently filed with the US Patent Office and the EPO for products derived from the neem tree for various claims, including fungicidal effects, extraction methods, storage of stable formulations of one of the active ingredients, contraceptives, medical uses, and insecticides. Overall, there were 90 patents for neem tree products.¹⁸

Dr Vandana Shiva, Director of the Research Foundation for Science, Technology and Ecology,

¹⁶Jajpura, Lalit, Bhupinder Singh, and Rajkishore Nayak. "An introduction to intellectual property rights and their importance in Indian Context." (2017).

¹⁷Joseph, Reji K. "International regime on access and benefit sharing: where are we now?." *Asian Biotechnology and Development Review* 12, no. 3 (2010): 77-94.

¹⁸Koul, Opendar, and Seema Wahab. "Neem biotechnology—A Synthesis." In *Neem: Today and in the new Millennium*, pp. 243-259. Springer, Dordrecht, 2004.

Ms Linda Bullard of the International Federation of Agriculture Movements and Ms Magda Aelvoet, Member of the Green Party of the European Parliament, filed a legal objection to the grant of this patent on the ground that the fungicidal effect of Neem Seeds hydrophobic extract has been known and used for centuries in India. Robert Larson, who was an importer of timber, filed a patent application in 1971. It was submitted based on the Neem pesticide. The exclusive patent right was transferred to the American W.R. Grace and Corporation in 1988. Chemical treatment for pesticides has been invented. Innovation could be transferred and widely used worldwide. On 14 September 1994, the European Patent Office granted patent No 436257 to the US Corporation W.R. Grace and the United States Department of Agriculture for a method for the control of fungi on plants through hydrophobic extracted Neem oil to the European Patent Office.¹⁹

(B) Basmati case

Rice is one of the fundamental aspects of the need of the people, especially for the people living in Asia. It is as a foundation and their food culture. Basmati rice is famous for its fragrance and aroma. The Basmati rice was famously known as the queen of fragrances or to be called perfumes²⁰The Basmati Rice was usually grown up and founded in the foothills of the Himalayas for over a thousand years. It has grown especially in climatic conditions where the content of moisture decreases. According to the Agricultural and Processed Food Products, Export Development Authority it has confers that India is the second-highest production of Rice after the world's number one product in China.²¹

The issue of Bio-piracy related to the Basmati rice was traced back to September 1997 when a Texas-based Company known as Rice Tec. Incorporation was granted a patent for the varieties of Basmati Rice by the US patent office. The Company, in its application, has claimed that the new varieties of Basmati Rice were interbreeding from one to another variety. Later on, the Basmati that was granted a Patent was renamed Texmati and Kasmati.²² It was after the renamed of the Basmati as Texmati and Kasmati the Rice Tec. Inc has become famous in the international market for selling the most Basmati Rice. Later, after the granting of Patented to Basmati Rice as Texmati, it started to affect the farmers in the country like India and Pakistan,

¹⁹ G., Hariharan. "Basmati, Turmeric and Neem-Patenting and Related Issues-Case Studies." *Law Rev. Gov't LC 2* (2002): 185.

²⁰ TED Case Studies. "India, US Basmati Rice Dispute Available at <http://www1.american.edu/ted/basmati.html> Last access on the 06th February 2022

²¹ Ibid

²² Utsav Mukherjee, "A Study of the Basmati Case (India - US Basmati Rice Dispute) The Geographical Indication Perspective" (2008) <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1143209 > Accessed on 06th February 2022

which India lost its international market for importing the Basmati Rice. Not only the two countries are suffering the loss but also the European Union, the United Kingdom, Middle East and West Asia also suffering from that.²³

The Granting of Patent to the Rice Tec. Inc company has been violating the fundamental fact of the long grain aromatic rice that was grown in India. The granting of a patent to that Company was objected to by the two Non-Government Organization (NGO), which are known as the Centre for Food Safety and Research Foundation for Science, Technology and Ecology; both these NGOs filed a petition in the Patent Office of US, not only this two NGO that objected the granting of a patent by the US Patent office to the Rice. Tec Inc company but also opposed by The Centre for Scientific Research and Agricultural and Processed Food Exports Development Authority²⁴.

There lead to numerous issues that were raised from this objection and granting of Patent of that Company they are as follows:

1. Whether the term Basmati is a generic one to describe aromatic Rice, or does it refer specifically to the long aromatic Rice grown in India and Pakistan?
2. Whether the strain developed by Rice Tec involve novelty?
3. Whether Rice Tec is guilty of biopiracy?
4. Whether US government's decision to grant a patent for the prized Basmati rice violates the International Treaty on Trade-Related Intellectual Property Rights (TRIPS)?
5. Whether the Basmati Patent should be revoked in the light of protests from India?

After the analysis of the above-mentioned issue, it was observed and established that the varieties of Basmati Rice were already in existence in India. As such, the patent should not have been granted to the Company for the varieties of Basmati. The Company of Rice Tech Incorporation gives up the claim of the patent application which were made by Rice Tech become a matter of Bio-Piracy. Also, the claims that were made by the Rice Tech company were rejected, despite all the evidence which was submitted by the IARI (Indian Agriculture and Research Institute) to the US Patent Office and the patent application was revoked by stating that it was a direct matter of theft with related to Basmati Rice.

Basmati Rice is a sample of Rice that belonged to Himalayan foothills situated in India.

²³Siddiq, E. A., L. R. Vemireddy, and J. Nagaraju. "Basmati rices: genetics, breeding and trade." *Agricultural Research* 1, no. 1 (2012): 25-36.

²⁴*Ibid*

Basmati Rice is one of the best examples that dealt with the loss of traditional and cultural value; it is because the patenting to the Company was not novel ideas or things. Rather it was Rice that was only imported to the US. The decision of the case is a great victory to the country like India and Pakistan. If the patent was not rejected, then the strong loss will suffer by these two countries, especially the economic losses.²⁵

(C) Turmeric Case

Turmeric is one of the native plants of South Asia that can mostly be found in the County of India from the very thousand years of civilisation. Turmeric is a plant that was used in the Indian System of medicine in all forms, including the use of paste, powder, decoction, oil, etc. The medicinal qualities such as wound healer, antiseptic, blood purifies, pain reliever and cosmetic purposes are mostly the common knowledge and method that was known by the indigenous people in India.²⁶ Turmeric's scientific name was commonly known as *Curcuma Longa*, the plant that comes from a ginger family. Turmeric in India has been used as a spice for colour while cooking. India is a country that has a diverse availability of traditional plants that can be used for medicinal purposes, so turmeric is no less than that; this plant can be used to heal wounded and for inflammation and sprains.

It was on the 28 March 1995, where the two-person namely Suman K. Das and Hari Har P. Cohly, who lived at the University of Mississippi Medical Centre, were granted a US patent which has a no as 541504 for the use of turmeric with related to the use of turmeric as a medicinal with related to the wound healing, later the patent was assigned to the University of Mississippi Medical Centre USA in the year 1995 by the US Patent Trademark Office for wound healing power concerning the turmeric which they claimed that is an original or novel innovation or invention. It was acknowledged that turmeric had been used for a long period by India as a medicine for various treatments such as sprains and inflammatory conditions.²⁷ The claim of the University about turmeric has no evidence of scientific research related to wound healing as was claimed by them.

It was, The Council of Scientific & Industrial Research (CSIR) New Delhi that challenged for the re-examination with the USPTO to reclaim. The CSIR has put an argument that turmeric has been used for many purposes by the Indians from ancient times. That so has also the power to heal the wounds which the use of it was known for a very long period and was not an

²⁵Subbiah, Sumathi. "Reaping what they sow: The basmati rice controversy and strategies for protecting traditional knowledge." *BC Int'l & Comp. L. Rev.* 27 (2004): 529.

²⁶Gupta, R. K., and L. Balasubrahmanyam. "The turmeric effect." *World Patent Information* 20, no. 3-4 (1998): 185-191

²⁷*Ibid*

invention as claimed by the USPTO. In the argument of CRIS, they had supported the documentary evidence related to the TK in India by providing a Sanskrit text and at the same time a paper that was published in the Journal of the Indian Medical Association, which was published in the year 1953. Also, it was challenged as a theft by the Indian government. It was in the year 1997, the patent was revoked by the USPTO after knowing that it was already used and existence in India for a very long period, and it has no novelty and innovation anymore.²⁸ Despite appeals by the holder of the patent, the USPTO maintain or hold up the objection made by the CSIR. Later the US patent Office revoked with related to this patent on 21 April 1998 after they found out that it has novelty in the invention, and it was found that turmeric has been used and known in India for centuries. These are the best examples that show how the medicinal plants and TK are being exploited by other people through Bio-Piracy.²⁹

IV. INDIAN LEGAL SCENARIO WITH RESPECT TO BIO-PIRACY

India has a tremendous legacy of written and oral TK about elements, conservation and different applications of biodiversity for the benefit of humans, animals, and the planet. This asset of knowledge is important for the preservation and human prosperity. Intellectual Property Rights is an unavoidable tool for the present globalised economy. "Its more extensive use should be empowered. Notwithstanding, such utilise should not prompt the getting of Intellectual Property Rights (IPR), which cannot be advocated for something that has been made by individuals, nor can revelations made on that premise happen without recognising the contribution of TK and sharing benefits to the makers of information fairly and equally."³⁰ Fostering innovation is one of the sustainable development goals set by the Indian government. "An India where Intellectual Property stimulates creativity and innovation for the benefit of all" is the vision of India's National IPR Policy. Several initiatives have already proven to foster innovation like the Make in India, Start-up India, Digital India and Skill India. The current laws were either enacted or revised after the TRIPS Agreement and are completely consistent with it. These laws along with various judicial decisions provide a stable and effective legal framework assurance and advancement of IPRs."³¹ Systems have been planned and executed to perceive and ensure India's immense Traditional Knowledge (TK) resources. Suitable administrative and institutional components have been put in place, important plans

²⁸Chengappa, Raj. "Patents: India wins a victory over turmeric but the war is on." India Today September 8 (1997).

²⁹ O'Connor, Bernard. "Protecting traditional knowledge: an overview of a developing area of intellectual property law." J. World Intell. Prop. 6 (2003): 677.

³⁰ *Ibid*

³¹ National-IPR-Policy. 2016. (available from <https://dipp.gov.in/sites/default/files/national-IPR-Policy20114October2020.pdf>)

are being carried out, and funds have been set aside for this purpose. In India, institutional mechanisms and programs directly related to the use of medicinal plants are under the Ministry of Ayurveda, Yoga and Natural Therapies, Unani, Siddha and Homeopathy (AYUSH). The main legislation related to traditional knowledge is the Biological Diversity Act, 2002 and The Patents Act, 1970, build up equity in the distribution of benefits with the traditional knowledge holders and the profits derived from the use of such knowledge, and prevented improper filing of a patent application for an invention based on traditional knowledge.³²

(A) India's biological diversity act, 2002

The Biological Diversity Act of 2002 (BDA) is part of an Indian law that emerged in response to compliance with the Convention on Biological Diversity (CBD), of which India is a ratified member. In fact, India has taken the lead among developing and developed nations both in introducing substantive legislation in conformance with the objectives of the CBD. It governs the conservation of biological diversity, sustainable utilisation and equitable sharing of benefits from the use of biological resources and knowledge. In terms of Section 6(1) of the Biological Diversity Act, 2002, "a person is prohibited from applying for any intellectual property in or outside India for any invention based on any research or information on a biological resource obtained from India, without first obtaining prior consent from the (National Biodiversity Authority) NBA. The BD Act makes admittance to TK and filling of applications for IPRs for products or invention that utilise TK, subjected to the approval of competent authorities."

(B) The Patents act, 1970

Indian law has adequate provisions for the protection of TK and Biological Resources. The Patents Act, 1970, defines that "invention means a new product or process involving an inventive step and capable of industrial application". Further, under Section 3(e) of the Patents Act, "a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or process for producing such substances" is not an invention and hence, not patentable. The Indian Patents Act also has a unique provision under Section 3(p), wherein "an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of a traditionally known component or components. The patents Act warrants that the subject matter claimed in a patent application must be novel. The inventive step is another cardinal principle of patentability". Often it is said to be the final gatekeeper of the patent system. The applications related to TK and/or biological

³² Mitra, A. "India: Biological Diversity Act, 2002 and Patenting of Biological Inventions In India–Part I (Section–6). 2017."

material shall also be critically examined with respect to requirements of full and particular disclosure of the invention, its operation or use and the method by which it is to be performed along with the best method of performing the invention by way of working examples known to the applicant in the complete Specification as provided under Section 10(4) (a) and (b) of the Patents Act.³³

(C) Protection of Plant Variety and Farmers' Rights Act, 2001

The Protection of Plant Varieties and Farmers' Rights Act, 2001 is a sui generis legislation in India providing protection for plant varieties and rights of farmers and is under the aegis of the Ministry of Agriculture. India, having ratified the Agreement on Trade-Related Aspects of the Intellectual Property Rights, has to make provision for giving effect to the agreement. To give effect to the aforesaid objectives, the Protection of Plant Varieties and Farmers' Rights Act, 2001, has been enacted in India. The Act "provides a system for the protection of plant varieties, farmers' and plant breeders' rights including rights in respect of their contributions made at any time in conserving, improving and making available plant genetic resources for the development of new plant varieties. It also facilitates the development of seeds and their commercialisation by farmers."³⁴

(D) National IPR policy

The government of India adopted the National IPR Policy in 2016 to facilitate the promotion, creation and commercialisation of IP assets through a Cell for IPR Promotion and Management (CIPAM) under the aegis of the Department for Promotion of Industry and Internal Trade (DPIIT) (IPR P, 2016). The national policy encourages researchers in public-funded academic and R&D institutions in IPR creation by linking it with research funding and career progression. It aims to raise awareness of the value of copyright for creators, the importance of their economic and moral rights and to promote India's rich heritage of traditional knowledge with the effective involvement and participation of those knowledge holders. The main focus of this policy is related to the slogan "Creative India; Innovative India", which subsequently is aligned to different government initiatives and missions in recent times that include "Make in India", "Atal Innovation Mission", "Start-Up India", and "Stand-Up India" promoting creativity, innovation and entrepreneurship in the country.³⁵

³³ Sekar, S., and S. Mariappan. "Usage of traditional fermented products by Indian rural folks and IPR." (2007).

³⁴ Nagarajan, S., S. P. Yadav, and A. K. Singh. "Farmers' variety in the context of Protection of Plant Varieties and Farmers' Rights Act, 2001." *Current Science* 94, no. 6 (2008): 709-713.

³⁵ National-IPR-Policy. 2016. available from <https://dipp.gov.in/sites/default/files/national-IPR-Policy20114October2020.pdf>

The policy suggests some measures, “such as expanding the ambit of the Traditional Knowledge Digital Library (TKDL) and expanded to include other fields besides Ayurveda, Yoga, Unani and Siddha. The policy also states that traditional knowledge holders will be provided necessary support and incentives for furthering the knowledge systems that they have nurtured through civilisation. The policy also seeks Activities for the promotion of traditional knowledge with the effective participation of holders of such knowledge. By documentation of such oral traditional knowledge will preserve the integrity of the said knowledge and traditional ways of life of the communities.”³⁶

(E) Traditional Knowledge Digital Library

In an attempt to provide maximum protection of its traditional knowledge, the Indian government launched the Traditional Knowledge Digital Library (TKDL) project in 2001 in collaboration with the Council of Scientific and Industrial Research, Ministry of Science and Technology and the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy and the Ministry of Health and Family Welfare of India. “The TKDL serves as a database of information on traditional knowledge in India, in languages and a format understandable by patent examiners at international patent offices. The database also facilitates prior art searches by translating prior art that exists only in indigenous South Asian languages.”³⁷ The success of this project can be proven in a report of the Council of Scientific and Industrial Research, which suggested that until 2016, TKDL has been successful in preventing the grant of more than 220 patents related to traditional Indian knowledge. The following patents offices have been granted access to the TKDL for carrying out prior art searches and patent examination:

- EPO (February 2009);
- USPTO (November 2009);
- Indian Patent Office (July 2009);
- German Patent Office (October 2009);
- United Kingdom Intellectual Property Office (February 2010);
- Canadian Intellectual Property Office (September 2010); and
- IP Australia (January 2011).

³⁶ Ibid

³⁷ Nadkarni, Abha, and Shardha Rajam. "Capitalising the benefits of Traditional Knowledge Digital Library (TKDL) in favour of indigenous communities." *NUJS L. Rev.* 9 (2016): 183.

V. CONCLUSION

The various cases study of Bio-Piracy could witness that the misused of Traditional Knowledge has been to a great extent. The misused of this Traditional Knowledge has witnessed not only the loss of the individual but also the economy of the country as India is a country in which the major of the population of the country belong to the rural areas, and as such, the use of the TK as a source of livelihood by the indigenous people is in a vast diversity. Indira Gandhi stated in one of her most popular speeches: “The idea of a better-ordered world is one in which medical discoveries will be free of patents, and there will be no profiteering from life and death.”³⁸ With the evolution of society, IP rights have formed an integral part of the development of the knowledge economy. Further, “if they are afraid of revision in the laboratory, the truth will never be released except by accident”, a highly potent phrase by Barbara W Tuchman, encapsulates the concept of biopiracy in its present form. Further, to protect the Traditional Knowledge national legislation should compulsorily require the following condition and they are:

1. Publicly reveal the source knowledge that is used, such as the use of a farmer variety in breeding a new variety, the use of a medicinal or aromatic plant to make goods, and the extraction of vegetable dyes from certain minerals and plants. Before using the bioresource, proof of prior informed consent in a particular standard format is needed.
2. It is important to remember that the scope of profit sharing can differ by sector.
3. Evidence of traditional knowledge should be considered in both oral and written forms of cultural knowledge, which will be passed on to third parties.
4. The punishment should act as a sufficient deterrent to the violation.

The call for traditional knowledge to be protected from abuse or misappropriation poses both policy and practical issues. The changing social climate, as well as the sense of historical dislocation that many societies are currently experiencing, can reinforce their resolve to preserve traditional knowledge for future generations. The task is to ensure that traditional communities’ intellectual and cultural contributions are sufficiently acknowledged, just as the technical importance of TK is increasingly recognised and its potential realised. This entails considering the intellectual property system’s needs and desires of conventional knowledge-holding societies. With the politicisation of science, indigenous protection has been put on the back burner. The debate around biopiracy is not a new one, yet it continues to remain as

³⁸ Reddy, G., and Dr Kadri. "Local Working of Patents: Law and Implementation in India." *Journal of Intellectual Property Rights* 18 (2013).

prevalent as it was over half a century ago. As the world remains divided in its threshold of morality and ethics, so does the scientific community. While inherent shortcomings in the said agreements can be easily resolved through amendments, the issue of biopiracy will continue to attract a horizon of views, subject to the inclination and sensibilities of individuals as well as communities. Lastly, a permanent solution will be achieved when the yawning gap between the developing and the developed countries is closed.
