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<u>A SOCIO-LEGAL STUDY OF LAW RELATING TO TRADITIONAL</u> <u>KNOWLEDGE AND BIODIVERSITY IN IPR IN PRESENT INDIA</u>

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ABSTRACT

Due to the fact that indigenous people have been responsible for the preservation and protection of a significant portion of the world's biodiversity, the preservation of traditional knowledge is absolutely necessary for the preservation and sustainable development of the environment. The awareness of these individuals is absolutely necessary for the protection and conservation of genetic resources as well as other types of bioresources. In a great number of other countries, the traditional knowledge of Indian items is considered to be a more valuable commodity than any other commodity. This is due to the fact that India is a location that is home to a vast quantity of useful materials, the majority of which are the outcome of conventional historical knowledge. The traditional knowledge of a variety of items in India ought to be safeguarded against the misuse of this information by other nations, and India needs to implement additional updates in the field of patenting Indian traditional knowledge in order to defend itself against this fact.

For the purpose of securing traditional knowledge (TK) through constructive and protective defense, this article discusses a variety of strategies that have been put into practice. In order to ensure the preservation of traditional knowledge, the Council for Scientific and Industrial Research (Government of India) has taken the initiative to record traditional knowledge (TK) in the Traditional Information Digital Library (TKDL). This has proven to be an extremely beneficial step in the process of safeguarding TK. Intellectual property rights (IPR) are exploited

as a weapon by bio pirates to steal conventional information and misuse biological resources. This arises as a result of specific deficiencies in the current system for IPR, which allows bio pirates to do so. This study ends with the considerations that emphasizes the necessity of incorporating a sui generis mechanism into the existing intellectual property rights framework.

Keywords- Intellectual Property, Traditional Knowledge, Biodiversity, legal framework

INTRODUCTION

Patent laws are territorial, which means that they are specific to the countries in which they are enacted. When we talk about patent laws, we are referring to these laws. Out of the 962 patent applications that were published in India in 2019, 71 were considered early publications, while 891 were considered ordinary publications. However, only 309 of these applications have been granted this week, while the other applications have been refused.

Anything that is unique, capable of industrial use, and is not frivolous (subject-matters acceptable for patentability) is considered to be an invention, as described in Section 2 (j) of the Patent Act (of India). Patents can be granted to those that come under the category of "Inventions," as defined by the Act. On the other hand, according to Section 3 and Section 4 of the Act, those that are unable to satisfy such standards (or that restrict the scope of subject topics that are eligible for patentability) are not patentable.

In accordance with the definition provided in Section 2 (j), the term "invention" refers to a new product or technique that is capable of application and involves an inventive step. It is important that the invention be completely original, considering that it has not been utilized or published in any region of the world.

The Patents Act of 1970 was enacted in 1972, serving as an amendment to and consolidation of the existing legislation pertaining to the Patents and Designs Act of 1911 in India. The Patent (Amendment) Act 2005 was enacted on January 1, 2005, to modify the previous patent system in India. This legislation expanded the scope of product patents to include all areas of innovation,

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including food, medicines, chemicals, and small-scale organisms. Furthermore, Section 3(d) of the aforementioned amending act of 2005 provides an intriguing overview of pharmaceutical item licenses in India. The Patent (Amendment) Act 2005 defines the concept of invention and explicitly states that any existing information or object cannot be eligible for patent protection. In the context of technical patents, "improvement" typically refers to invention that directly builds upon an existing patent.¹ In a broader context, an improvement might be conceptualized as a modification that modifies certain aspects of the original innovative patent, rather than merely providing an alternative approach to achieve the same outcome.

The term "biological diversity" or "biodiversity" refers to the variety of living species that can be found on earth, including those that are found in the air, water, and land conditions. In addition to the millions of different races, local variations of species and subspecies, and ecological processes and cycles that bind organisms into populations, communities, ecosystems, and ultimately the entire biosphere, biodiversity encompasses other aspects of life as well. Genetic diversity, species diversity, and ecological diversity are the three primary levels at which biodiversity is recognised. The term "genetic diversity" refers to the variance that exists within each species, "species diversity" refers to the variety of species, and "ecosystem diversity" refers to the range of ecosystems and habitats. In accordance with the taxonomy described above, there are 1.75 million species that have been identified in the world's biodiversity. These species can be found in a variety of ecosystems, each of which contains a unique combination of members. in a variety of environments, combinations. A mere 2.7 lakhs of these 1.75 million species are classified as belonging to the plant kingdom. The majority of human needs, including food, clothing, shelter, medicine, fodder, and industry, are met by less than nine thousand different plant species. Approximately 900 of these species have been domesticated for agricultural purposes, and out of these, approximately 168 species are farmed exclusively for the purpose of food production and agricultural production. A significant number of plant variations are dwindling at a startling rate as a result of the growing industrialisation of agriculture and the growing dependence of humans on plant species.

¹ "Kriti Singh- Critical analysis of section 3(d) of Indian patent act, 1970, s 2021; 3(2): 73-77 https://www.multisubjectjournal.com/article/90/3-2-16-226.pdf, Last visited 1st April 2024".

The preservation of biological resources and the responsible utilisation of those resources in accordance with the indigenous knowledge systems and practices is deeply ingrained in the Indian way of life and culture. As a consequence of this, India possesses a robust set of institutions that are engaged in mapping biodiversity and undertaking. taxonomic studies. It is largely the responsibility of the Botanical Survey of India, which was formed in 1890, and the Zoological Survey of India, which was created in 1916, to conduct surveys of the flora and animals of India. There are a number of specialized institutions and universities, including the National Institute of Oceanography in Goa, that are contributing to the further strengthening of the taxonomy database. According to the findings of the survey conducted by these agencies, there are 46,000 plant species and 81,000 animal species that inhabit 70% of the total geographical area of the country.

The vast majority of India's bioresources are connected to the traditional knowledge systems that are utilised by the people of India for a variety of activities that are necessary for their subsistence. Activities such as agriculture, fishing, medicine, and artisanal work are included in this category. A progressive drop in the use of these knowledge systems has occurred as a result of the introduction of new technologies.² The establishment of the regime of intellectual property rights (IPRs), which is a system that is founded on the legal theory and economic philosophy of the western world, is one of the most important outcomes of the industrial revolution that occurred in the western world. Intellectual property rights are intended to guarantee incentives to innovators, and it is asserted that they have been a significant driving factor behind the rapid rise of the industrial sector in developed countries. The primary reason for their development was to safeguard mechanical and chemical discoveries, for which the identification of novelty, creative step, and innovator is rather straightforward.

Among the several types of intellectual property rights (IPRs), patents are the limited monopoly that are awarded to inventors for their innovations and unique works, typically for a period of twenty years to be exact. Generally speaking, patents are considered to be a method that can be utilised to foster innovation and invention within a society. An innovation that is to be given a patent must satisfy three patentability requirements, which are outlined in Article 27(1) of the

² Available at: <u>https://nopr.niscpr.res.in/bitstream/123456789/1781/1/JIPR%2013(4)%20326-335.pdf</u>

TRIPS Agreement. These requirements are as follows: (a) the invention must be novel; (b) it must include an innovative step or it must be non-obvious; and (c) it must be capable of being applied in industrial settings³.

In addition to the traditional realm of mechanical and chemical discoveries, the intellectual property rights framework has also been expanded to include biological resources. It has been suggested that the modern intellectual property rights system, in its current form, has primarily developed as a response to a need that arose in Europe in the aftermath of the industrial revolution. Furthermore, it is said that this regime does not, in theory, offer protection for the knowledge that is held by traditional communities that are in the public domain. An extensive number of individuals have voiced their opinion that the imposition of the existing intellectual property rights systems will not be acceptable for the protection of traditional knowledge. The Trade Related Intellectual Property Rights Agreement (TRIPS) is incompatible with the international human rights norms and puts the rights of indigenous and local communities at risk regarding their natural resources and the knowledge linked with those resources. In addition, the current intellectual property rights law does not offer protection for inventions that are founded on previously known information, such as information that is in the public domain. The current intellectual property rights system, according to the opinions of many people, is not well suited to reward ideas that have originated from a community of people. Additionally, the TRIPS Agreement does not include any specific reference of the innovations and traditional knowledge that are considered to be in the public domain. As a matter of fact, intellectual property rights are utilised as a legal way to appropriate the traditional knowledge found inside communities. In certain countries, patents are granted for a variety of things, including processes, products, inventions, naturally occurring plants and animals, human genetic material, microorganisms, and parts or components of plants and animals, including genes, cells, DNA sequences, and biological, microbiological, and oo- biological processes.

Patents that are granted on non-original innovations, particularly those that are associated with traditional medicines, which are based on what is already a part of the traditional knowledge of the majority of developing and mega-biodiverse countries without the approval of those

³ Article 27(1) of TRIPS Agreement

countries have been raising a great deal of worry. As a matter of fact, traditional knowledge (TK) cannot be separated from the community through the transfer of ownership to another individual or oragnisation. This is due to the fact that the knowledge is a component of their unique and collective identity, and it is contextualized inside the community itself, rather than being external to it.

SCOPE AND LIMITATIONS

Scope of the Study:

- Examination of Indian IPR Legislation: The study will analyses current Intellectual Property Rights (IPR) legislation in India, including the Patents Act, the Biological Diversity Act, and the Geographical Indications Act, to evaluate their effectiveness in safeguarding traditional knowledge and biodiversity.
- Socio-Economic Effects on Indigenous Communities: The study will examine the socioeconomic implications of IPR legislation on indigenous people, specifically regarding their rights to traditional knowledge, and the effects of these laws on their cultural legacy, livelihoods, and resource access.
- 3. Global Impact on Indian Legislation: The study will examine the impact of international agreements, including the Convention on Biological Diversity (CBD) and the Nagoya Protocol, on the Indian legal framework and assess their practical implementation at the national level.
- 4. Role of the Traditional Knowledge Digital Library (TKDL): The research will evaluate the efficacy of the TKDL in safeguarding traditional knowledge and biodiversity, specifically in its capacity to thwart biopiracy and to ensure the recognition and protection of knowledge possessed by indigenous groups.
- 5. Free, Prior, and Informed Consent (FPIC): The scope will encompass an examination of the integration and enforcement of the FPIC concept within India's legislative framework concerning the use of traditional knowledge, with an emphasis on the rights of indigenous peoples and local communities.

 Case Studies: The research may encompass case studies of legal conflicts, occurrences of biopiracy, or effective implementations of the existing IPR framework in safeguarding traditional knowledge and biodiversity in India

Constraints of the Research:

- 1. Geographical Limitations: The study will concentrate on the legal frameworks and socioeconomic situations in India, potentially lacking a thorough examination of other nations or an in-depth international comparative analysis.
- Scope of Legal Analysis: The research will concentrate on intellectual property rights laws and their relationship with traditional knowledge and biodiversity; however, it may not comprehensively cover all facets of the legal framework, including administrative procedures, specific legal cases, or intricate local implementation.
- 3. Access to Data: The study may encounter difficulties in obtaining comprehensive data from indigenous groups, governmental bodies, or private organisations, particularly regarding confidential agreements or active legal proceedings.
- 4. The study will concentrate on formal, written rules and regulations, although it may not comprehensively encompass the informal legal systems, customs, or indigenous practices that coexist with formal intellectual property rights frameworks.
- 5. The complexity of FPIC implementation may hinder the research's ability to comprehensively assess the level of FPIC application in practice, due to a scarcity of tangible, publicly accessible instances of both successful and unsuccessful FPIC processes concerning traditional knowledge utilization.

RESEARCH QUESTIONS

- 1. In what manner do contemporary Intellectual Property Rights (IPR) regulations in India safeguard traditional knowledge and biodiversity?
- 2. What are the socio-economic effects of intellectual property rights legislation on indigenous communities in India that depend on traditional knowledge and biodiversity?
- 3. To what degree does the current legal system in India acknowledge and safeguard the rights of indigenous and local populations concerning traditional knowledge and biodiversity?

- 4. What is the impact of global IPR treaties, such as the Convention on Biological Diversity (CBD) and the Nagoya Protocol, on India's local legislation regarding traditional knowledge and biodiversity conservation?
- 5. In what manner does India's Traditional Knowledge Digital Library (TKDL) aid in safeguarding traditional knowledge and biodiversity within the existing intellectual property rights framework?
- 6. In what manner does the Indian legal system guarantee the free, prior, and informed consent (FPIC) of indigenous groups when their traditional knowledge is utilized or commercialized?

RESEARCH OBJECTIVES

- 1. To evaluate India's current Intellectual Property Rights (IPR) laws' protection of traditional knowledge and biodiversity and their strengths and limitations.
- 2. To study how IPR laws affect indigenous populations in India's livelihoods, culture, and access to traditional knowledge and biological resources.
- 3. To assess the extent to which India's legal system protects indigenous and rural populations' traditional knowledge and biodiversity rights and identify shortcomings.
- The study aims to examine how international IPR treaties, such as the CBD and Nagoya Protocol, affect India's laws and policies for preserving traditional knowledge and biodiversity.
- 5. To examine how India's Traditional Knowledge Digital Library (TKDL) preserves and protects traditional knowledge and biodiversity within the IPR framework and prevents biopiracy and unauthorised use of traditional resources.
- 6. To evaluate Indian legal mechanisms that ensure Free, Prior, and Informed Consent (FPIC) for indigenous communities when their traditional knowledge and biodiversity are used or commercialized, and to identify any issues with FPIC implementation.

HYPOTHESIS

The Traditional Knowledge Digital Library (TKDL) in India has made a significant contribution to the conservation of traditional knowledge and biodiversity within the context of intellectual property rights (IPR) by lowering the number of instances of biopiracy and leading to improved acknowledgement of indigenous methods.

RESEARCH METHODOLOGY

The research approach employed in this study is a doctrinal research method. Legal research technique is a systematic approach that emphasizes the examination and analysis of existing legal principles, legislation, cases, and other legal documents. It derives conclusions and ideas from reputable legal authorities and sources.

- Text Examination: The doctrinal technique relies on the examination of legal sources, including statutes, regulations, case law, legal commentaries, and scholarly literature. Researchers focus on extracting semantic significance and understanding legal concepts from these writings.
- Statutory interpretation: Involves the examination of statutes and regulations in order to ascertain the intended meaning of the legislature. Researchers analyze the phrasing employed in statutes and regulations, as well as the historical judicial interpretations of such legal texts.
- Legal comments and secondary sources: Such as scholarly publications, are examined to gain fresh insights and alternative viewpoints on legal principles. Secondary sources provide additional context and analysis that go beyond primary legal documents.

LITERATURE REVIEW

a) Kriti Singh- Critical analysis of section 3(d) of Indian patent act 1970, International Journal of Multidisciplinary Trends 2021; 3(2): 73-77⁴- The fundamental concept is that the Indian Patent Act, section 3(d), does not permit patent protection for merely discovering anything, unless the substance in question expresses substantial efficacy in regards to the known material. This section is being challenged as being in violation of

⁴ "Kriti Singh- Critical analysis of section 3(d) of Indian patent act 1970, International Journal of Multidisciplinary Trends 2021; 3(2): 73-77, https://www.multisubjectjournal.com/article/90/3-2-16-226.pdf, Last visited 13th April 2024".

the TRIPS agreement. The argument is based not only on the fact that it does not offer any particular rules for incremental innovation, but also on the fact that it does not offer the standard protection that is offered by TRIP to all kinds of innovations. Therefore, the topic of the entire research revolves around the disadvantages of section 3(d) in comparison to Indian patent.

- b) Elizabeth Verkey, law of patents, Eastern Book Company (ISBN 8170128706) 2005, 95-159- The author has analysed the section 3(d) and provided the fundamental concept that some innovations are not patentable, with special reference to patents over improvements. This is in opposition to the TRIPS agreement, which states that it is in violation of the TRIPS agreement.
- c) Aditya Kan- An Attempt at Quantification of 'Efficacy' Factors under Section 3(d) of the Indian Patents Act, Journal of Intellectual Property Rights Vol 18, July 2013, pp 303-315⁵- In order to assist patent authorities in determining whether or not a pharmaceutical invention is patentable or eligible for a patent, this policy paper makes an attempt to construct a theoretical model that is extraordinarily straightforward. While the proposed model (which is based on a more expansive meaning of the term "efficacy") has not yet been subjected to empirical testing, it has the potential to serve as a very helpful guidance, thereby reducing the amount of arbitrariness and ambiguity that is associated with the application of the "efficacy" criteria as outlined in Section 3(d). A comprehensive overhaul of the existing patents regime in India has been advocated, and this model has been recommended as part of that reform. Nevertheless, this change at the domestic level must be accompanied by a separate reform at the international level in order to be considered complete.

⁵ "Aditya Kan- An Attempt at Quantification of 'Efficacy' Factors under Section 3(d) of the Indian Patents Act, Journal of Intellectual Property Rights Vol 18, July 2013, pp 303-315, https://docs.manupatra.in/newsline/articles/Upload/02C35991-70A8-4244-B7E0-2A33C0A152A9.pdf, Last visited 13th April 2024".

- d) Reddy, T Prashant, & Live Law (2020) "Live Law," published on 9th Dec⁶- The task of drafting a treatise or commentary on Indian patent law is one of the most difficult things that can be accomplished simultaneously. Because of the comparatively low levels of patent litigation and the extremely limited number of precedents that can be cited from Indian courts, this is the case. Since the Indian patent law was revised in order to bring it into conformity with the Agreement on Trade Related Intellectual Property (TRIPs), which has been in effect for the past fifteen years. This book discusses the important decisions that were made in relation to the Patent Act of 1970.
- e) **Tulasi GK, Rao BS. A detailed study of patent system for protection of inventions. Indian J Pharm Sci. 2008 Sep**⁷- The term "intellect" refers to the products of the brain. These creations are considered to be property because they have a high value from a business perspective. Patents are a form of intellectual property that can be used to protect inventions, provided that the invention under consideration is innovative, non-obvious, useful, and enabled. The TRIPS agreement was developed by the World commerce Organization in order to facilitate fair commerce among its member countries. by signing the agreement with the World Trade Organization, India has taken the crucial first step and altered itself to meet the needs of the global community. With the help of a comprehensive study of the prior art, the purpose of this article is to educate pharmaceutical experts, particularly those working in the field of research and development, about the process of designing inventions. This will help save both time and money. It is possible to achieve a comprehensive understanding by providing information regarding the origin of the patent system, the existing governing bodies, the role that they play, and the Act that is protecting the patent system.
- f) K Venkataraman, Intellectual Property Rights, Traditional Knowledge and Biodiversity of India- India is a mega-biodiverse nation characterized by various

⁶ Reddy, T Prashant, & Live Law (2020) "Live Law," *Live Law*, https://www.livelaw.in/book-reviews/patent-law-cases-materials-book-review-166978.

⁷ "Tulasi GK, Rao BS. A detailed study of patent system for protection of inventions. Indian J Pharm Sci. 2008 Sep;70(5):547-54. doi: 10.4103/0250-474X.45390. PMID: 21394248; PMCID: PMC3038276".

combinations of habitats. India's biodiversity manifests at three levels: species, genetic, and ecological, often linked to traditional knowledge and behaviour. The decline of biodiversity and the commodification of bioresources and related knowledge have raised significant concerns, particularly when intellectual property rights are utilised to assert monopolistic control. Negotiations at both international and national levels on the safeguarding of traditional knowledge and the conservation of biological resources are currently focused on various aspects of implementing the Convention on Biological Diversity (CBD), 1992. India, as a signatory to the Convention, was the first to implement it by implementing the Biological Diversity Act, 2002, which established a three-tiered institutional system. Nevertheless, the Act requires further elucidation regarding implementation matters such as benefit sharing. This article examines and elucidates several of these challenges and concerns, thereby proposing further measures for the successful execution of the Act.