AN ANALYSIS OF THE ISSUES AND CHALLENGES IN THE PROTECTION OF INDIGENOUS KNOWLEDGE FROM BIO-PIRACY IN INDIA

R.Alagu Mani, Tamil Nadu Dr. Ambedkar Law University (Soel)

R.Dinesh Kumar, Tamil Nadu Dr. Ambedkar Law University (Soel)

ABSTRACT

The issue of bio-piracy poses significant challenges to the protection of indigenous knowledge in India, where traditional knowledge systems are deeply intertwined with the country's rich biodiversity. This paper explores the multifaceted dimensions of bio-piracy, highlighting how corporations exploit indigenous knowledge for commercial gain without proper recognition or compensation. Notable cases, such as the patenting of turmeric and neem by foreign entities, exemplify the misappropriation of traditional practices that have been cultivated over centuries. Despite existing legal frameworks aimed at safeguarding traditional knowledge, such as the Traditional Knowledge Digital Library (TKDL), systemic inadequacies and lack of enforcement continue to undermine these efforts. The paper argues for comprehensive reforms that enhance community engagement, legal recognition, and international cooperation to effectively combat bio-piracy and ensure equitable benefit-sharing with indigenous communities. Ultimately, protecting indigenous knowledge is not only a matter of legal rights but also crucial for preserving cultural heritage and promoting sustainable development.

Keywords: Traditional Knowledge, bio-piracy, patent, indigenous, sustainable development

CHAPTER-1 INTRODUCTION

Human beings are considered as the most intelligent and distinct creatures in the entire universe because of their critical thinking and analytical power. They have the unique ability of complex reasoning, using multifarious language, solving difficult problems, and possess very highly developed brains that set them apart from all other animals. In ancient times, the human intellect was not considered as property like goods and chattels, which can be tradable. Human, knowledge was freely shared with mankind. No one claimed copyright or patent for any creation, innovation, or invention. The knowledge shared in the ancient Hindu and other religious scriptures illustrate many unknown facts which were not documented or preserved properly.

In old days property means the lands and goods. But over time due to phenomenal advancement in the socio-economic and political sphere, society gradually changed into a knowledge- based society. Now days, the knowledge holders receive more importance and recognition than in old age. People, who may not be very highly qualified scientists, academicians, or research scholars but possess unique traditional knowledge in the fields of biodiversity (usefulness of plants, animals, and micro- organisms), agriculture, health treatment, traditional cultural expressions, and folklore, have been considered as the holders of intellectual property rights.

The Paris Convention (1883) for the Protection of Industrial Property, acknowledged patents, trademarks, and industrial design as the intellectual properties in the world. Subsequently, the Berne Convention (1886) included Copyright and neighbouring right like artistic, musical, and literary works as intellectual properties. With the establishment of the World Intellectual Property Organization (WIPO) at Geneva Switzerland in 1967, the term 'intellectual property' got official recognition at the international level. Recently the traditional knowledge (TK) recognized as the emerging form of intellectual property.

Unlike other forms of Intellectual Property, traditional knowledge is a community-owned collective property. It forms an intrinsic part in the life of the indigenous people, who possess unique knowledge, and practices relating to their distinct cultural set up. Traditional knowledge is a basic mean of their existence and survival. It based on experience, empirical observation, and interaction with the natural environment. Such knowledge is evolved gradually, sustained,

and passed on from generation to generation within a community. It does not necessarily fulfill the criteria for protection under the usual framework of other intellectual property systems, which provide protection for a limited time. However, attempts have been made for defensive protection under other Intellectual Property Laws Traditional Knowledge attracts global attention only in recent years when it received importance from the international commercial world. It is profusely available in developing country like India, which is having a vast treasure of bio- diversity related traditional knowledge. The growing importance of such knowledge makes it more vulnerable to unauthorized exploitation, unlawful appropriation and bio-piracy of genetic resources. The need to protect and promote traditional knowledge in the developing and the least developed countries becomes a matter of great concern at the national as well as international forums.

Common men viewed traditional knowledge as the local customary practices, home remedies, and cultural expression (folklore) of the indigenous communities. But its growing demand in various fields especially in agriculture, and the pharmaceutical industries, forced the national and international bodies to develop necessary legal instruments for its preservation and effective protection. So far as the national law while emphasizing the need for enacting effective law to prevent bio-piracy and exploitation of associated Traditional Knowledge within and outside the national boundary. It proposes for further in-depth study regarding the wholesome preservation, promotion, and protection of Traditional Knowledge as an important element of Intellectual Property Rights.

1.2 SIGNIFICANCE OF THE STUDY:

- Indigenous knowledge is a vital component of the cultural identity of local communities. It embodies centuries of wisdom regarding biodiversity, sustainable practices, and traditional healing methods.
- Understanding the challenges surrounding bio-piracy can guide the development of robust legal frameworks that recognize and protect indigenous rights.
- The existing intellectual property (IP) laws often inadequately address the unique nature of traditional knowledge, which is typically communal rather than individualistic.
- A focused study can help identify gaps in current legislation and propose necessary reforms to safeguard IK more effectively.

- The unauthorized appropriation of indigenous knowledge can lead to significant economic losses for local communities.
- By analyzing these issues, the study highlights the potential for equitable benefit-sharing mechanisms that ensure indigenous peoples receive recognition and compensation for their contributions to industries such as pharmaceuticals and agriculture.

1.3 REVIEW OF LITERATURE:

1. **P.V. Valsala G. Kutty, National Experiences with the Protection Expressions of Folklore/ Traditional Cultural Expression: India, Indonesia and The Philippines for WIPO:** The study emphasizes the growing recognition of the need to protect expressions of folklore, which encompass cultural manifestations such as music, dance, art, and traditional knowledge. These expressions are vital for preserving cultural identity and heritage among indigenous communities. The literature indicates that the lack of adequate legal frameworks leaves these communities vulnerable to exploitation and bio-piracy, where their traditional knowledge is appropriated without consent or compensation.
2. **S.K.Verma & R. Mittal, Intellectual Property Rights: A Global Vision, Indian Law Institute, 2006, 38:** The literature underscores that intellectual property rights are essential for safeguarding the creations of the mind, including inventions, artistic works, and symbols. The authors emphasize that effective IPR systems encourage innovation and economic growth while ensuring that creators can benefit from their work. This foundational understanding sets the stage for discussing how these rights apply to traditional knowledge.
3. **Daniel Gervais, The Trips Aggrement: Drafting History And Analysis 2nd ed. (Sweet & Maxwell), 2003, 590:** Gervais delves into the drafting history of the TRIPS Agreement, detailing the negotiations that took place during the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) from 1986 to 1994. The literature emphasizes how the inclusion of intellectual property rights into the multilateral trading system marked a significant shift in global trade policy. Gervais discusses the motivations behind this inclusion, particularly the lobbying efforts by developed countries to establish higher standards for IP protection.

4. **Daniel Gervais, The Trips Agreement: Drafting History And Analysis 4th ed. (Sweet & Maxwell), 2012:** Gervais provides a thorough exploration of the historical background leading to the establishment of the TRIPS Agreement. He discusses the negotiations that took place during the Uruguay Round of GATT, emphasizing the political and economic motivations behind incorporating intellectual property into trade discussions. The literature highlights Gervais's active role in these negotiations, which adds a unique perspective on the complexities involved in drafting the Agreement.
5. **M.D. Nair, Opinion on TRIPS, WTO and IPR: Protection of Bioresources and Traditional Knowledge, Journal of Intellectual Property Rights, Vol. 16, January 2011, 35-37:** Discusses the TRIPS Agreement as a pivotal element in international trade law, emphasizing its role in establishing minimum standards for intellectual property rights (IPR) among WTO member states. The article outlines how TRIPS integrates various forms of IP protection, including patents, copyrights, and trademarks, while also addressing the unique challenges posed by traditional knowledge and bioresources. Nair critically examines how these standards may conflict with the rights of indigenous communities over their traditional knowledge.

1.4 RESEARCH GAP:

While there are existing laws and initiatives, such as the Traditional Knowledge Digital Library (TKDL), there is a gap in comprehensive studies evaluating their effectiveness. Research is needed to assess how well these frameworks protect indigenous knowledge and identify areas for improvement, particularly in relation to international legal standards.

1.5 OBJECTIVES OF THE STUDY:

- To study the issues involved in protecting Traditional Knowledge as an emerging form of intellectual property, and
- To assess the need of enacting a Sui generis law to overcome the challenges involved in the protection of India's Traditional Knowledge or professional qualifications possess unbelievable knowledge regarding agriculture, health remedies, astrology, and weather forecasting, which are peculiar and unique to their community.
- Even they can make accurate weather predictions about any upcoming natural calamity (cyclone or storm), like highly qualified scientist working under advanced scientific

laboratories. The local people possess such knowledge since time immemorial. Such knowledge based on experience, empirical observation, and interaction with their natural environment. In rural areas often people prefer to approach the 'Quack' (semi-skilled medical practitioner) for health issues.

- Those Quacks possess traditional knowledge about the medicinal properties of various plants and other natural products. Nowadays such traditional knowledge of local people uses in the fields of pharmaceutical, agricultural, biotechnological, and genetic research.

1.6 HYPOTHESIS:

Despite the presence of legal frameworks in India aimed at protecting indigenous knowledge, systemic challenges such as lack of awareness, inadequate enforcement, and socio-economic disparities hinder their effectiveness against bio-piracy.

1.7 RESEARCH QUESTIONS:

1. How effective are current intellectual property laws in recognizing the rights of indigenous communities over their traditional knowledge?
2. What are the best practices from successful case studies in other regions that could be adapted to improve traditional knowledge protection in India?
3. How can traditional knowledge be effectively integrated into modern legal frameworks?

1.8 RESEARCH METHODOLOGY:

This research employs a qualitative research design, focusing on a combination of doctrinal (legal) and empirical (field-based) methods. The doctrinal approach will involve analyzing the existing legal frameworks, case laws, and international conventions. The empirical approach will involve fieldwork, including interviews with stakeholders such as indigenous communities, government officials, and legal experts.

1.9 LIMITATIONS:

(i) The period of research is very short which is a narrow period. The topic which I have chosen for the research paper is wider and also within this short time, we need to cover a wide area.

(ii) The topic is a wider topic which has to be done through various sources, but I have used a very limited source.

1.10 SCHEME OF THE STUDY:

Chapter 1: Introduction

- Overview of Indigenous Knowledge: Definition and significance in cultural identity and biodiversity.
- Historical Context: Evolution of intellectual property rights and recognition of traditional knowledge.
- Problem Statement: Introduction to bio-piracy and its implications for indigenous communities.

Chapter 2: International Regime for Protection of Traditional Knowledge

- Global Frameworks: Examination of international agreements such as the Convention on Biological Diversity (CBD), World Intellectual Property Organization (WIPO) guidelines, and Food and Agriculture Organization (FAO) initiatives.
- Analysis of Existing Legal Instruments: Critical appraisal of how these frameworks address the protection of traditional knowledge and bioresources.
- Community Rights: Discussion on traditional community rights and their role in protecting indigenous knowledge.

Chapter 3: National Legal Framework in India

- Current Legislation: Overview of Indian laws related to intellectual property, including the Biological Diversity Act and Traditional Knowledge Digital Library (TKDL).

- Effectiveness of Legal Protections: Evaluation of how well these laws protect indigenous knowledge from bio-piracy.
- Case Studies: Analysis of notable cases involving the appropriation of traditional knowledge (e.g., neem, turmeric).

Chapter 4: Challenges in Protecting Indigenous Knowledge

- Systemic Inadequacies: Identification of gaps in legal frameworks and enforcement mechanisms.
- Socio-Economic Factors: Exploration of how socio-economic disparities impact the effectiveness of protections for indigenous communities.
- Awareness and Education: Discussion on the lack of awareness among indigenous communities regarding their rights.

Chapter 5: Conclusion

- Summary of Findings: Recap of key insights gained from the study.
- Future Directions: Suggestions for further research and action needed to improve protections against bio-piracy.

CHAPTERS-2 INTERNATIONAL REGIME FOR PROTECTION OF TRADITIONAL KNOWLEDGE:

The demand for an effective protection of traditional knowledge has gained momentum, either through the application of the traditional IPR system or by means of a new sui generis system such as traditional community rights or community property rights. There is also a need to enable communities to harness traditional knowledge for their upliftment and growth. Thus the present review deals with legal framework at the international and national perspectives and makes a critical appraisal of CBD, FAO, WIPO, Biodiversity Act, etc. for protection of traditional knowledge[1].

The importance of protecting the knowledge, innovation and practices of indigenous and local communities is increasingly recognized in international forums. The immediate need is to ensure that the benefits of cumulative innovations with traditional knowledge go to their holders while enhancing their socio-economic development.[2] The first effort to protect Traditional Knowledge (TK) under the IP regime was a joint initiative taken by WIPO and the United Nations Educational, Scientific and Cultural Organization (UNESCO) in 1978 which led to the Protection of Expressions of Folklore against Illicit exploitation and other prejudicial Actions in 1982. Since then, the protection of Traditional Knowledge has gained increasing attention with the adoption of the Convention on Biological Diversity (CBD) in 1992. The CBD, through its Article 8 (j) has broadened the scope and mandate of protection with wider objectives. There has been lot of effort to protect Traditional Knowledge by inter-governmental bodies dealing with IP, environment and even human rights control to the indigenous and local communities over Traditional Knowledge, namely, World Trade Organization (WTO) and its Council for Trips, World intellectual Property Organization (WIPO), Food and Agriculture Organization (FAO), United Nations Conference on Trade and Development (UNCTAD) and World Health Organization (WHO).

[1] G. Chin Khan Muan "Traditional Knowledge And Convention Of Biological Diversity, available at http://www.aippfoundation.org/R+ID/TK%20&%20cbd.pdf.
[2] J. O. Berkey, Implications of the WTO Protections for Food Geographical Indications, American Society of International Law (April, 2000) Accessed on15th May 2016.

CONVENTION ON BIOLOGICAL DIVERSITY (CBD):

The convention on Biological Diversity (CBD) was concluded on 5 June 1992. It was the result of discussions at the Rio de Janeiro 1992 under the United Nations Environment Programme (UNEP). The CBD administered by UNEP, establishes principles for the protection of the environment while ensuring ongoing economic development, emphasizing conversation of biodiversity, sustainable use, and fair and equitable benefit sharing of the use of genetic resources 2.[3] CBD is an important re-assertion of the sovereign rights of the States over their biological resource. Article 8 (j), seems to affirm, that the holders have rights over their knowledge, innovations and practices, whether or not they are capable of being protected by IPRs. If they are not capable of being protected by the existing IPR system, still there is an obligation for the governments to safeguard these entitlements either through a new IPR law or by over legal or policy measures. These duties should also extend to uses of TK, innovations and practices.

The CBD also recognizes the importance of traditional use of genetic resources in the sustainable preservation of biological diversity. It establishes access to the biological transfer from the industrialized countries, and asserts that IPRs must not conflict with the preservation and sustainable use of biodiversity 5 . Similarly, it also incorporates provisions which provide for the encouragement, development of exchange and use of indigenous and traditional knowledge and technology in the spirit of CBD.[4]

FOOD AND AGRICULTURE ORGANIZATION (FAO):

The FAO has wide range of activities relating to access to genetic resources, their sustainable use, promotion, and protection of Traditional Knowledge activities in the Forest Department, including the programs on non-wood forest products and communities foresting deserve special attentions. In the recent years the biggest development was International Treaty on Plants Genetic Resources for Food and Agriculture (ITPGRA), popularly known as International Seed Treaty. It was adopted on 30th Nov 2001 by FAO Conference at its 31st Session in Rome with no country voting against.[5]

[3] Kiichiru Hayashu, The International Environment For Access To Genetic Resources, available at http://www.mri.co.jp/E/PAPER/PP01022300.pdf.
[4] V. Elizabeth, "TK - The Changing Scenario in India" Law.ed.ac (University of Edinburg) accessed on 14th May 2016 at Online
[5] Article 1.1; The international treaty on plant genetic resources for food and agriculture.

ITPGRA is a comprehensive international agreement in harmony with CBD which aims at guaranteeing food security through conservation, exchange and sustainable use of the world's plant genetic resources for food and agriculture, as well as the fair and equitable sharing of benefits arising from its use. The treaty recognizes the right of the farmers and local communities, who have been in the centre of origin and diversity, in conserving, improving and making available these resources.[6] The Treaty also emphasizes the need to protect Traditional Knowledge relevant to plant genetic resources for food and agriculture in order to implement farmer's right (Article 9.2).

It also makes the national government responsible for bringing about equitable participation in benefit sharing arising from the utilization of plant genetic resources for food and agriculture, amongst farmers. The treaty provides for funding strategy to mobilize funding for priority activities, plans and programmes, in particular in developing countries and countries with economics in transitions, taking into account the Global Plant of Action adopted in Leipzing in 1996. The Treaty, however, is limited in its scope. It is principally aimed at preventing the loss of agro-biodiversity rather than biodiversity in general, and establishes the principle of farmer's rights and not the rights of local communities in general.

UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT (UNCTAD):

UNCTAD's member states decided to address the protection of Traditional Knowledge as part of UNCTAD's work in the area of trade environment and development. UNCTAD has addressed the issue of protection of Traditional Knowledge from the trade and development perspective. In UNCTAD, the emphasis has been on exchanging national experience on policies and measures to protect Traditional Knowledge for trade and on identifying policies to harness Traditional Knowledge for trade and development. In October 2000, UNCTAD member states convened an Expert Meeting in Geneva. It accepted the importance of Traditional Knowledge in the promoting sustainable development of national and international economics, and therefore it recommended UNCTAD to do further work on its protection.

[6] Leipzig declaration of conservation and sustainable utilization of plant and genetic resources for food and agriculture. Available at < http://www.fao.org/docrep/meeting/443/pq6-6396.

WORLD TRADE ORGANIZATION (WTO):

In various communications to the IPRS Council of the WTO during the last few years, it has time and again been emphasized by India that the rights of the holders of TK to share benefits arising out of innovation based on their knowledge and the associated bio-resources should be recognized in the TRIPS Agreement. This, according to them, calls for harmonization of the provisions of TRIPS with those of CBD. It is apprehended by India and others that in the absence of clear provisions in TRIPS Agreement with the member's obligations under CBD, implementation of the TRIPS Agreement may allow facts of bio-piracy and thus result in systemic conflicts with the convention. With a view to avoid such conflicts an amendment of the TRIPS Agreement to accommodate some essential elements of CBD is considered necessary by India and allies.[7] Hence, this group of countries has proposed in the WTO that the TRIPS Agreement should be amended in order to provide that members shall require that an applicant for a patent relating to biological materials or to TK shall provide, as a condition to acquiring patent rights:

a) Disclosure of the source and country of origin of the biological resources and of the traditional knowledge used in invention;

b) Evidence of prior informed consent through approval of authorities under the relevant national regimes; and

c) Evidence of fair and equitable benefit sharing under the national regime of the country of origin.

Even though the recognition of the subject under Doha Ministerial Declaration was initially perceived to be a significant step forward in resolving the issue, the actual chain of development on the matter in the TRIPS Council in the Post-Doha era, has not given much scope for the India and allies to cheer. The principal resistance to the proposal of amendments of TRIPS for incorporating the new patent disclosure requirements to bring TRIPS in line with the CBD has come on behalf of the United States. The US maintains that while the objectives of TRIPS and CBD are distinct, there is no conflict between them and that these agreements can and should be implemented in a mutually supportive manner. The US clings to the argument that the introduction of the proposed new patent disclosure requirements will not ensure the

[7] World Trade Organization (WTO), Kent Nnadozie , "African Perspectives on Genetic Resources : A Handbook on Law and Politics "accessed 18th May 2016.

achievement of the objectives envisaged by CBD and may furthermore have significant negative consequences.

For instance, it is argued that the new patent disclosure requirements would add new uncertainties in the patent system.[8] Particularly where the sanctions for non-compliance include invalidation of a patent, this would create a "cloud" of uncertainty over the patent right over the patent right by opening a new avenue for litigation and other uncertainties. These, according to the US, would undermine the role of the patent system in promoting innovation and technological development. In light of these concerns, the US is not convinced that the proposed new disclosure requirements in patent applications are an appropriate solution to the problem.

Instead, it maintains that the CBD's objectives on access to biological resources and TK, and on benefit sharing, could best be achieved through establishment of separate national legal and other framework (such as contractual arrangements) outside the patent system that can more directly and effectively regulate conduct relevant to these issues. Furthermore, a bio-piracy, it is argued, is a global problem and more often than not, involves the acquisition of material in one country and seeking of a patent in another. This means that relying on national measures alone is not sufficient to address the bio-piracy problem.

Hence, to ensure the effectiveness of the contemplated obligations on the applicants, a positive and mandatory obligation needs to be imposed on the member countries of the WTO to require the disclosure by patent applications in their territories of the source and country of origin of the biological resources and/ or TK used in inventions. Such a positive and mandatory obligation, according to them, could be introduced into the TRIPS Agreement either by appropriately amending the existing provisions or by introducing a new article in the Agreement.

WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO):

WIPOs work on TK and folklore began in 1978 when WIPO developed a sui generic model for national protection of folklore jointly with UNESCO. In 1998 WIPO launched a new programme, including, interacting fact finding mission to 28 countries in IP and TK, which produced a global report on IP needs and expectation of TK holders. In its 26th session WIPO General Assembly established IGC. The IGC's action so far has focused on trying to understand

[8] D.P. Mittal, Indian Patent Law/153, 1999.

the needs and expectations of local community ascertaining the adequacy of current methods for protecting Traditional Knowledge and surveying proposals to enhance such protection. It has also done a commendable work of producing impressive number of documents, including the model clauses for genetic resources contracts, a toolkit for documentation of Traditional knowledge protection, and work on elements of a possible sui generis system of protection of traditional knowledge.

The WIPO is also taking steps to enhance the coverage of documented traditional knowledge in the minimum documentation of the Patent Cooperating Treaty (PCT), and to expand the International Patent Classification (IPC) for accurate and focused searching for relevant traditional knowledge during the patent examination process. WIPO in its fourth session of IGC, made some notable contributions. It discussed the notion of sui-generis protection of Traditional Knowledge and also some of the factors that might make it difficult to define precisely a legal regime for Traditional Knowledge. It also pointed out to an important fact, that very diversity of conceptions of Traditional Knowledge, embracing technical Traditional Knowledge and expressions of folklore, might dilute the clarity and effectiveness of any sui generic system. At this session, important observations were made regarding the rational for protection. Firstly, IP protection of Traditional Knowledge would enable Traditional Knowledge holders to preserve their identity against any use they do not wish their Traditional Knowledge to be given.

The second rationale for protection is the fact that the Traditional Knowledge protection increases legal scrutiny and predictability to the benefit not only of Traditional Knowledge holders, but also of the society as a whole, including firms and research institutions who are potential partners of Traditional Knowledge holders. The third rationale for protection concerns economic development and poverty alleviation, it the communities desire the formalization and recording of traditional communities' intangible asserts then it can transform them into capital, thus facilitating the establishment of commercial venture within traditional communities. The reason being that many traditional communities who live in apparent poverty are actually rich in knowledge, but their knowledge, not being subject of formal property law is prone to commercial misappropriate by others. Furthermore, once recognized through titles, Traditional knowledge can be used as collateral security for giving traditional communities facilitated access to security.

WORLD HEALTH ORGANIZATION (WHO):

The World Health Organization, the United nations specialized agency for health was established on 7th April 1948. The WHO involvement in Traditional knowledge relates to its work on traditional medicine.[9] The WHO objective as set out in its constitution, is the attainment by all people of the highest level of health, as the economic and trade value of Traditional Knowledge, particularly the knowledge of traditional medicine and medicinal plants, in becoming increasingly recognized, more and more WHO members states have become concerned with the need to protect it and to secure the fair and equitable sharing of any benefit derived from its utilization. WHO's Traditional Medicine Strategy 2002-2005, has four main pillars, namely:

a) Policy- Integrate Traditional and complementary or alternative medicine (TM/CAM) with national healthcare system.

b) Safety, efficiency and quality: provide evaluation, guidance and support for effective regulation.

c) Access: ensure availability and affordability of TM/CAM, including essential herbal medicines.

d) Rational use: promote therapeutically- sound use to TM/CAM by providers and consumers.

At present WTO is supporting clinical studies on anti-malarials in three African countries, the studies are revealing good potential for herbal anti-malarials. In Tanzania, WHO, in collaboration with China, is providing technical support to the government for the production of anti-malarials derived from the Chinese herb Artemisia annua. Local production of medicines will bring the price of one dose down from US $6 or US $7 to an affordable US $2

[9] Dr. Xiaoruyi Zhang, WHO Traditional Medicine Safety.

CHAPTER-3 NATIONAL REGIME FOR PROTECTION OF TRADITIONAL KNOWLEDGE:

India has not brought out any Traditional Knowledge specific legislations but measures have been adopted by India such as Biodiversity Act, 2002 and Protection of Plant variety and Farmers Right Act, 2001 and the Patent (Amendment) Act, 2005 to give effect to its obligations under the TRIPS agreement, CBD and International Treaty on Plant Genetic Resources for Food and Agriculture 2004. TTPGRFA has reiterated India's stand in different intergovernment bodies working on the protection of Traditional Knowledge. In India, preparation of village-wise Community biodiversity Registers (CBRs) for documenting all knowledge, innovations and practices has been undertaken in a few States.

An exercise has been initiated to prepare to easily navigate computerized database of documentation Traditional Knowledge relating to use of medicinal and other plants, known as Traditional knowledge Digital Library (TKDL).

Such digital database would enable Patent Office's all over the world to search and examine any prevalent use or prior art, and thereby prevent grant of patents and biopiracy. In India provisions have been made for protecting Traditional knowledge in Biodiversity Act 2002, Protection of Plant varieties and Farmer's rights (PPVFR) Act, 2001 and Patent (Amendment) Act, 2005.[10] India has not brought out any Traditional Knowledge specific legislations but measures have been adopted by India such as Biodiversity Act, 2002 and Protection of Plant variety and Farmers Right Act, 2001 and the Patent (Amendment) Act, 2005 to give effect to its obligations under the TRIPS agreement, CBD and International Treaty on Plant Genetic Resources for Food and Agriculture 2004. TTPGRFA has reiterated India's stand in different inter-government bodies working on the protection of Traditional Knowledge.[11]

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[10] . Section 16 of the Protection of Plant Varieties and Farmers Rights Act, 2001.
[11] P. Brahmi, S. Saxena, & B. S. Dhillon, The Protection of Plant Varieties and Farmers Rights Act of India, Current Science,Vol. 86 (3), 10 February 2004, 392.

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THE BIOLOGICAL DIVERSITY ACT, 2002

The Biodiversity Act 2002 primarily addresses access to genetic resources and associated knowledge by foreign individuals, institutions or companies, to ensure equitable sharing of benefits using out of the use of these resources and knowledge to the country and the people. The Act stipulated norms for the access to biological resources and Traditional knowledge based in three ways 22-26: 1. Access to biological resources and Traditional Knowledge to foreign citizen, companies and NRI based on "Prior approval of National Biodiversity Authority," 2. Access to Indian Citizens, companies, Associations and Organizations registered in India on the basis of "Prior intimation to the State Biodiversity Board", concerned, and 3. Exemption of prior approval or intimation for local people and communities, including growers and cultivations of biodiversity, vaids and hakims, who have been practicing, indigenous medicines.[12]

There is no requirement under the legislation for seeking permission of the National Biodiversity Authority for Carrying out research, if it is carried out in India by Indians, as well as under the collaborative research projects that have been drawn within the overall policy guidelines formulated by the Central government.[13] The only situation that would require permission of the NBA are

(i) when the results of any research which has made use of the country's biodiversity is sought to be commercialized

(ii) when the results of the research are shared with a foreign institution or individual wants access to the country's biodiversity for under taking research.

The Act, subject to Section 21 and Rule 20 of the Biodiversity Rules, insists up on including appropriate benefit sharing provisions in the access agreement and mutually agreed terms

[12] P. Narayana, Intellectual Property Law, Eastern Law House, 2013,396.
[13] Section 3 and Section 4 of The Biological Diversity Act 2002.

related to access and transfer of biological resources or knowledge occurring in or obtained from India for commercial use, bio-survey, bio-utilization or any other monetary purposes. The Authority shall develop guidelines and shall notify the specific details of benefit sharing formula in an official gazette on a case-to-case basis. The time frame and quantum of benefits to be shared shall be decided on case-to-case based on mutually agreed terms between the applicant, authority, local bodies, and other relevant stakeholders, including local and indigenous communities.[14]

One of the suggested mechanisms for benefit sharing includes direct payment to persons or group of individuals through district administration, if the biological material or knowledge was accessed from specific individuals or organizations. In cases where such individuals or organizations could not be identified, the monetary benefits shall be paid to the National Biodiversity Fund. Five percent of the benefits shall be earmarked for the Authority or State Biodiversity Board towards the administrative service charges.[15]

THE PROTECTION OF PLANT VARIETIES AND FARMERS' RIGHTS (PPVFR) ACT, 2001

The PPVFR Act 2001 and the PPVFR Rules 2003, deal primarily with the protection of plant breeder's rights over the new varieties developed by them and the entitlement of farmers to register new varieties and also to save, breed, use, exchange, share or sell the plant varieties, which the latter have developed, improved, and maintained over many generations. The Act is a deviation from the 1991 UPOV Model and can regarded as an alternative 'sui generis' system that accord protection of the rights of the formal innovations of a plant breeder and informal knowledge system and traditional plant varieties of the farmers as well. The important provisions contained in this Act relevant to ABS are those on the protection of farmer's rights and the mechanisms suggests for compensation or benefit-sharing for the contributions of local communities or farmers in the development of a new variety.

The Indian legislation on PPVFR is the singular attempt made by a developing country to give effect to the concept of Farmers' Rights as provided for in the International Treaty. Although this act has several limitations, it nonetheless provides a model of an effective sui generis

[14] Section 7 of The Biological Diversity Act 2002.
[15] M. K. Bhandari , Law Relating to Intellectual Property Rights", Central Law Publications , 2006, 217.

system for protection of plant varieties that WTO members are expected to put in place in fulfilment of their commitment to the Agreement on TRIPS.

THE PATENT (AMENDMENT) ACT, 2005

India has utilized the flexibility of TRIPS in the Patent (Amendment) Act, 2002. This Amendment has introduced a new obligation (in Section 10 (4) of the principle (1970) Act, which stipulates the requirements of a patent application) on the patent application, when used in an invention. Such a provision is perfectly compatible with TRIPS, since, it is not violating other provisions of this Agreement.[16] The Patents (Amendment) Act 2005, passed by the parliament recently has also introduced some important provisions. Dealing with the post-grant opposition further stipulates that at any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of patent, any person interested may give notice of opposition to the Controller in the prescribed manner on certain specified grounds.

The eleven grounds stipulated for such post-grant opposition include the following two grounds, That the complete specification does not disclose or wrongfully mentions the source and geographical origin of biological material used for the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere. These two provisions ensure protection of the rights of the source country of a biological material or traditional knowledge of local or indigenous community, and thereby enabling recognition and reward of source countries and traditional knowledge holders through appropriate benefit sharing mechanisms. Thus, provisions included in the Indian Patents Act in conjunction with the PIC and benefit sharing requirements incorporated in the Biological Diversity Act 2002 create sufficient room for combating the biopiracy threats at the national level in India.

Nevertheless, the problem remains that existence of a similar protective shield for Indian bio-resources Traditional Knowledge cannot be guaranteed under the national patent laws of other countries. The Agreement does not make it obligatory for the member countries to include in their respective patent laws provisions aimed at protecting the bio-resources and Traditional Knowledge of the country of origin against biopiracy. However, the protection of these precious

[16] The Patent (Amendment) Act , 2002.

assets cannot be guaranteed until and less certain compulsory provisions are included in TRIPS in this regard, which all the Member countries would be obliged to comply with.

CURRENT STATUS OF IPR PROTECTION WORLDWIDE:

As of 1988, 53 countries statutorily excluded plants and 54 excluded animals from patent protection (WIPO, 1990, Annex II). These include the members of the European Patent Convention (EPC) which in Article 53(b) excludes patents for "plant or animal varieties and the essentially biological processes for the production of plants and animals". Written in the pre-biotechnology days, the interpretation of that phrase has proven complex over the years. Several patents have been granted bases on an interpretation that "variety" refers to a variety in a "fixed form" so that a development which was applicable across multiple varieties could be patented. Most recently, the European Patent Office appeals ruling on a Plant Genetics System patent rejected coverage for the plant and seeds (EPO, 1995). The significance of that decision will not become clear for some time. The bulk of the other countries are developing nations, many of which have language similar to the EPC.[17]

As noted, there are presently 30 members of UPOV, with all but Argentina, Chili, Uruguay, and South Africa being developed countries. A number of additional countries have national PBR laws, including Colombia, Taiwan, Kenya, and Chile, among others. Details on the operation of those laws are limited. Membership in a national convention standardizes the conditions of protection to a large degree. Standardization of patent and trademark laws is assured in part by the Paris Convention of 1883 with its 100 plus members. Among the key provisions are national treatment which stipulates that foreigners must be granted the same rights as nationals. Additionally, the right of priority stipulates that an application filed in any member country establishes that filing date for all other countries for a period of one year. The filing date is critical for the bulk of countries which follow the first-to-file system. The major difference is the USA which uses the first-to-invent procedure (Lesser, 1987b). The World Intellectual Property Organization (WIPO), a specialized agency of the United Nations, which oversees administrative and harmonization responsibilities administer the Paris Convention.

[17] D. Vivas, A. Eugui, Bridging the Gap on Intellectual Property and Genetic Resources in WIPO's Intergovernmental Committee (ICG), Issue Paper No. 34, January 201.

The Traditional Knowledge Digital Library

The Traditional Knowledge Digital Library (TKDL) serves as a crucial tool in combating bio-piracy by protecting India's rich heritage of traditional knowledge, particularly in the field of medicinal plants. Here are the key advantages of TKDL in addressing bio-piracy:

1. Prevention of Erroneous Patents

TKDL provides patent examiners with access to a comprehensive database of traditional knowledge, enabling them to identify prior art effectively. This helps prevent the granting of patents that lack novelty, which has been a significant issue for Indian medicinal systems. For instance, since the establishment of TKDL, there has been a notable decline in patent applications related to Indian medicinal systems, with a reported 44% reduction at the European Patent Office (EPO) alone.

2. Cost-Effectiveness

Opposing patents traditionally incurs significant costs and time—averaging between USD 200,000 to USD 600,000 and taking 5 to 7 years to resolve. In contrast, TKDL allows for pre-grant objections based on prior art evidence at minimal or no cost. This expedited process can take as little as 3 to 20 weeks, significantly reducing financial burdens on stakeholder.

3. Facilitation of Access for Patent Examiners

The TKDL database is structured in multiple languages (English, French, German, Japanese, and Spanish), bridging linguistic barriers between traditional knowledge and patent examination processes. This accessibility enhances the quality of searches conducted by patent offices globally. By providing information in a format that patent examiners can readily understand, TKDL improves the scrutiny of patent applications involving traditional knowledge.

4. Reduction in Patent Applications

Since the implementation of TKDL, numerous patent applications have been withdrawn or set aside based on evidence from the database. For example, over 324 applications have been successfully challenged using TKDL data without incurring legal costs. This proactive approach has established TKDL as an effective deterrent against bio-piracy.

5. Integrated Global Biopiracy Watch System

TKDL includes a monitoring system that tracks patent applications related to Indian traditional knowledge globally. This allows for timely detection and intervention against potential misappropriation, ensuring that corrective actions can be taken swiftly and efficiently.

6. Support for Indigenous Rights

By safeguarding traditional knowledge through TKDL, India reinforces the rights of indigenous communities over their cultural heritage. This not only protects their economic interests but also acknowledges their contributions to global biodiversity and medicine.

Traditional Knowledge Digital Library Status:

A boon or curse in the battle against bio-piracy There was great exhilaration in the atmosphere on India's proposal of setting up a TKDL as the genesis of Indian effort to fight bio-piracy as a joint venture of CSIR, Ministry of Science and Technology and Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH), Ministry of Health and Family Welfare to assuage the organized structure and recovery of the traditional knowledge. The TKDL squad incorporated representatives from many fields viz., traditional medicine, patent, information technology (IT), scientists and technicians which were involved in documentation of the TK available in local community arena in the form of surviving written records and texts associated to Ayurveda, Unani, Siddha and Yoga, in digital format in five global languages.

The digital Library proved copulative between TK (referred in public records) and Patent evaluators at international platform and hence valuable in preventing the granting of indefensible patents [38] and thus, endorse the preservation, promotion, dissemination and exercising suitable use of TK. So far TKDL database comprises about 2.12 Lakh medicinal formulations (Ayurveda: 82,900; Unani: 1, 15,300; Siddha: 12,950), from 148 books available in public domain, and the database exists in 34 million A4 size pages. On 29th June 2006, under a non-disclosure agreement, Government of India has sanctioned the access of TKDL databases by International Patent Offices.[18]

[18] M.D. Nair, Opinion on TRIPS, WTO and IPR: Protection of Bioresources and Traditional Knowledge, Journal of Intellectual Property Rights, Vol. 16, January 2011, 35-37.

If we give a look at other side of the TKDL operation, it will be unwrapped that TKDL has made the situation more vulnerable by opening the gates to the multinational companies to manipulate the TK as an invention or novelty. US companies are fiddling with the traditional knowledge and gaining several patents by presenting the old knowledge in a new packet. The digital library will act as a pathfinder for such companies who just have the mean motive of earning money by exploiting the already existing original medicinal information. International companies will just make dewey-eyed alterations which add up to cost addition and assist them to get the patent in their lap. The digital library will easily serve the rare and indigenous information on the platter to British and US private companies. TKDL may provide the crucial and indigenous knowledge to corporate sector inadvertently which will in one way or another demolish the fundamental and financial rights of traditional people to use their own ancestral knowledge.

CHAPTER-4 BIO-PIRACY IN INDIA AND RELEVANT CASELAWS:

A major fraction of the world's population, mostly the underdeveloped areas and rural communities, still rely on the indigenous medicinal knowledge of locally available plants for not just their medical requirements (Shankar 1997; Bhattacharya 2014), but also for food and agriculture (Bhattacharya 2014).Traditional knowledge not only includes the recorded knowledge of plants for medicinal use, but also takes into account the oral knowledge that has been passed on from ancestors (Bhattacharya 2014). There has been great scientific interest in the lifestyle, knowledge and culture of indigenous people since the traditional knowledge acquired by rural communities over a number of years forms their basic cultural identity. The people living in local communities maintaining fairly traditional lifestyles are termed as "indigenous people" (Andrews 2012).[19]

A majority of the Indian population (70%) is dependent on land-based occupations, forests, wetlands and marine habitats for ecological and cultural sustenance (Kothari and Patel 2006). With an estimated 163 horticultural and crop varieties which have originated in the country, India is one of the world's eight major centers of crop diversity and has centuries' old traditional knowledge (Sudha 2014). Even today, about two-third of Indian population relies on indigenous knowledge of biological resources and have conserved their knowledge and culture through their traditional lifestyles and local economies. More than 7500 species of plants are utilized for the traditional purposes in India.[20] The plant genetic resources were considered to be a common heritage until the last century (Brush 2005). Common heritage refers to "the treatment of genetic resources as belonging to the public domain and not owned or otherwise monopolized by a single group or interest" (Brush 2005; Andrews 2012).

India's Combat against Biopiracy Many cases have been registered in India where attempts have been made to steal the indigenous knowledge from India due to its easy access which affect food security, livelihood of indigenous people and even cause changes in consumers' choice. The persons involved in plundering natural resources from the developing and less developed countries prosper, while the persons from whom benefits are derived suffer since they are paid only petty amounts and sometimes are not even paid at all (Bhattacharya 2014).

[19] Andrews, D. 2012. Traditional Agriculture, Biopiracy and Indigenous Rights, 2nd World Sustainability Forum, 1-30 November, 1-12.

[20] Anup, S. 2002. Food Patents–Stealing Indigenous Knowledge? Genetically Engineered Food, http://www.globalissues. org/EnvIssues/GEFood/FoodPatents.asp (Retrieved on 03-07- 2018).

'Biopiracy' term is generally used when multinational corporations or companies profit from the medicinal and agricultural uses of plants known to indigenous or native societies and fail to compensate those communities" (Dwyer 2008; Andrews 2012).[21]

Alternatively, it refers to "appropriation, generally by means of patents, of legal rights over indigenous biomedical knowledge without compensation to indigenous groups who originally developed such knowledge" (Sudha 2014). There have been a number of cases of biopiracy of traditional knowledge from India, commonly observed in plant varieties such as Haldi (Turmeric), Basmati, Neem etc. (Bhattacharya 2014). According to a study conducted in 1999, global market value of industries using biological and genetic material is estimated between $500-800 billion. The economic value of traditional knowledge in the herbal medicine and pharmaceutical sector is estimated to reach around 5 trillion by 2020 (Sudha 2014; Shah 2014).[22]

Basmati rice case:

In 1997, the Texas based RiceTec Inc. was granted a patent **(# 5663484)** by the USPTO on Basmati rice lines and grains. The Research Foundation of Science, Technology and Ecology (RFSTE), India and co. filed an appeal in Supreme Court of India in public interest on March 4, 1998, which compelled Government of India to file a "Request for Re-examination" against the aforementioned patent at USPTO to re-establish the validity of the ―Basmati Rice Lines and Grains¦ patent. The financial and trade interests of basmati rice exporters in the country appeared to be a significant contributory factor to this request.[23] In reality, the Indian Government was unaware of the patent application filed, until it was protested against The United Kingdom for registering Ricetec's trademark "Texmati" in 1998.

India's claim was based on the fact that genuine Basmati rice breed can only be produced from the indo-gangetic plains of India and Pakistan due to the distinctive and complicated union of cultivation factors and genetic code of the Basmati varieties. Due to these developments there arose a diplomatic crisis between United States (US) and India, with India threatening to take

[21] Aoki, K. 2009. Symposium: When Worlds Collide: Intellectual Property at the Interface Between Systems of Knowledge Creation: Panel II: Knowledge Creations Systems on the National Stage: "Free Seeds, Not Free Beer": Participatory Plant Breeding, Open Source Seeds, and Acknowledging User Innovation in Agriculture. 77. Fordham L. Rev. 2275.

[22] Bhattacharya, S., Chattopadhyay, D.J. and Mukhopadhyay, A. 2013. Changing Dimensions of Food Security in a Globalized World: A Review of the Perspectives for Environment, Economy and Health. International Research Journal of Environmental Sciences, 2(3): 67-73.

[23] Athawale RG. IPRs as a Tool for Empowerment of Small Entrepreneurs, Artisans & Craftsmen. India: SME World; May 2010. http://www.smeworld.org/story/top-stories-104/ipr-empowerment-tool-34.php

the case to World Trade Organization (WTO) as violation of TRIPS leading to US embarrassment. The original patent application was a skilfully drafted document embracing 20 claims of which US Ricetec was compelled to drop 15 claims. This was a grand victory for Indian cultivators who could have been deprived tremendous financial rewards from the patent.

Neem Case:

In 1985, Robert Larson obtained a patent on the extraction process of his preparation of neem seed extract called as Margosan-O and later sold it to a US company WR Grace. In 1995 United States Department of Agriculture (USDA) and the US chemical major W.R. Grace gained patent rights (European Patent Office patent #436257) for an extraction technique of neem oil for its fungicidal properties. W.R. Grace possessed patents for neem-based bio pesticides, including Neemix for use in agriculture.[24] In more than 200 species of insects, Neemix overpower and crush their growth and feeding behaviour. After gathering their patents and clearance from the Environmental Protection Agency (EPA), Grace started commercializing its product by setting up manufacturing plant in collaboration with P.J. Margo Pvt. Ltd in India.

The commencement of campaign in opposition to bio-piracy pertained to Neem (Azardictica indica) was carried by the RFSTE India, in collaboration with the International Federation of Organic Agriculture Movements and Magda Aelvoet, Green member of European parliament in 1993 in contrast to patenting of a natural living resources and its products.[25] The information relating to application of neem as fungicide, insect repellent, soaps, cosmetics and contraceptive was known to Indians for more than thousand years and proved to be the structural stone to object the US claim for Neemix. The revocation of patent by the European Patent Office (EPO) in May 2000, was based on the evaluation of proofs of prior art and it was revealed that there is no involvement of any inventive step.

[24] Boisvert V., Caron A., The convention on biological diversity: An institutionalist of the debates, J Econ Issues 2002; 36:1:151- 66.
[25] Crops and robbers. actionaid.org.uk. http://www.actionaid.org.uk/doc_lib/crops_robbers.pdf.

The Indian Ginseng –Ashwagandha Case:

In May 2001, American and Japanese firms filed applications for the issue of patents in their favour regarding formulations or extracts of Ashwagandha. The patent application by Japanese firm Pola Chem Tech was regarding topical skin ointment for cosmetic purposes and to promote fertility whereas the US based the New England Deaconess Hospital was successful in getting a patent relating to its use to alleviate the symptoms regarding arthritis. On 27th July, 2006 Natreon Inc, an America based multinational company filed a patent application in the EPO on Ashwagandha's age long use in treatment of anxiety induced stress, depression, insomnia, gastric ulcers and convulsions titled ―Method of Treatment or Management of Stress¦.(European patent #1906980). Out of several patents granted in favour of Ashwagandha, India was successful in revoking only one.[26]

In order to crush their attempt, Indian authorities replied back on 6th July 2009 by submitting evidences from Traditional Knowledge Digital Library (TKDL) and some documents dating back to 12th century. In our traditional ayurvedic system of medicines, the parts of this wonder plant find a well-recognized status as aphrodisiacs, diuretics and for restoring loss of memory.[27] As a result of the breathless efforts, on 25th march 2010, EPO decided to dismiss the American's firm claims over the Indian Ginseng.

[26] Ngokkuen C. and Grote U., Challenges and opportunities for protecting geographical indications in Thailand, Asia-Pacific Development Journal 2012;19:2; 93-123.
[27] Kumar P. Bio piracy, GM seeds and rural India.
http://www.globalresearch.ca/index.php?context=va&aid=13820. [Updated on 2009 June 02.

CHAPTER- 5 CONCLUSION

The protection of indigenous knowledge from bio-piracy in India is fraught with challenges that require urgent attention. Strengthening legal frameworks through the establishment of sui generis systems, enhancing awareness among indigenous communities, ensuring equitable benefit-sharing, and fostering international cooperation are essential steps toward safeguarding traditional knowledge. Now days, the knowledge holders receive more importance and recognition than in old age. People, who may not be very highly qualified scientists, academicians, or research scholars but possess unique traditional knowledge in the fields of biodiversity (usefulness of plants, animals, and micro- organisms), agriculture, health treatment, traditional cultural expressions, and folklore, have been considered as the holders of intellectual property rights.

In India, in order to check bio-piracy an exercise has been initiated to prepare easily navigable computerized database of documented TK relating to use of medicinal and other plants, known as Traditional Knowledge Digital Library (TKDL). However, documentation of TK is only one of the means of giving recognition to knowledge holders. Mere documentation may not enabler sharing of benefits out of the use of such knowledge unless it is backed by some kind of mechanism for protecting knowledge. Documentation of TK may only serve a defensive purpose, namely that of preventing the patenting of this knowledge in the form of which it exists.

National level mechanisms and legal provisions to prevent bio-piracy as well as to install informed consent mechanisms to ensure reward to TK holders should also be given international recognition for their effective implementation and for their enforcement in other countries. Thus, there is a need for development of an international mechanism for protecting TK. Positive and defensive protection measures along with development of sui generis law may perhaps be the best and immediate options for countries like India to provide IP rights to Traditional Knowledge holders.

India is prone to Bio-piracy because of its being the earth's richest biodiversity. Bio-piracy provides scarce biological resources to the monopoly control of corporations thus depriving local communities the benefits of its use. It creates market monopolies and excludes the original stakeholders (farmers) from their rightful share to local, national and global markets. In order to restrict bio-piracy there is a desperate need to make amendments in TRIPS, Biodiversity Bill, Seed Bill and Patent Bill as these are enforced in a hurry to comply with global changes.

Ayurvedic courses should be upgraded to accommodate patent awareness among professional, academicians and researchers.

Patenting of vital plant resources poses a threat to the consumers and with the advent of technological interventions, the intellectual property rights of indigenous people have become a vital issue. However, with spread of awareness, the patent protection for various plant varieties has been provided by several national and international acts and conventions in the recent past. GIs should also address the rights of our farmers to use, save, exchange, and improve their seeds for domestic production or protection of our indigenous knowledge. Bio-piracy is a serious tool used by highly desirous pharmaceutical and biotechnological firms which should be restricted and opposed and demands attention and efforts from government, Non-government organizations, scientists and publishers in public and national interests.

An attempt has been made in this article to support the developing countries who are victim of bio-piracy by the highly covetous developed countries who are toying with the traditional knowledge of the indigenous residents under the veil of legality-the international Patent System. Membership in a national convention standardizes the conditions of protection to a large degree. Standardization of patent and trademark laws is assured in part by the Paris Convention of 1883 with its 100 plus members. Among the key provisions are national treatment which stipulates that foreigners must be granted the same rights as nationals. Additionally, the right of priority stipulates that an application filed in any member country establishes that filing date for all other countries for a period of one year.

The filing date is critical for the bulk of countries which follow the first-to-file system. The major difference is the USA which uses the first-to-invent procedure (Lesser, 1987b). The World Intellectual Property Organization (WIPO), a specialized agency of the United Nations, which oversees administrative and harmonization responsibilities administer the Paris Convention.

To combat bio-piracy effectively, it is crucial to engage all stakeholders—including government bodies, legal experts, NGOs, and indigenous communities—in collaborative efforts aimed at creating a robust protective environment for indigenous knowledge. Only through such comprehensive strategies can we ensure that the rights and contributions of indigenous communities are recognized and respected in an increasingly globalized world.

RECOMMENDATIONS:

1. **Comprehensive Review of Existing Legal Frameworks**: Conduct a thorough analysis of current laws and regulations affecting indigenous knowledge protection in India, including the Biological Diversity Act, the Patents Act, and the Traditional Knowledge Digital Library (TKDL). Evaluate the effectiveness of these frameworks in preventing bio-piracy and protecting the rights of indigenous knowledge holders.
2. **Sui Generis Systems Development**: Investigate the potential for creating a sui generis legal framework tailored specifically for the protection of traditional knowledge. This should include provisions for prior informed consent and equitable benefit-sharing mechanisms. Compare existing models from other countries that have implemented similar systems to identify best practices.
3. **Impact Assessment of Bio-Piracy**: Analyze case studies of bio-piracy incidents in India to assess their impact on local communities, biodiversity, and the economy. Evaluate how these incidents have influenced public policy and legal reforms related to indigenous knowledge.
4. **Stakeholder Engagement**: Examine the roles and responsibilities of various stakeholders, including government agencies, NGOs, indigenous communities, and corporations, in protecting indigenous knowledge. Develop frameworks for collaborative governance that involve all stakeholders in decision-making processes.
5. **Awareness and Capacity Building Programs**: Research the current state of awareness among indigenous communities regarding their rights and the mechanisms available for protecting their knowledge. Propose educational initiatives aimed at empowering these communities to assert their rights and engage with legal frameworks effectively.
6. **International Mechanisms for Protection**: Investigate existing international agreements (e.g., CBD, WIPO) that relate to the protection of traditional knowledge and assess their effectiveness. Explore the feasibility of developing an international treaty or agreement specifically focused on protecting indigenous knowledge from bio-piracy.

7. **Economic Analysis of Benefit-Sharing Models**: Conduct an economic analysis of various benefit-sharing models that could be implemented to ensure fair compensation for indigenous knowledge holders. Assess how these models can be integrated into existing legal frameworks to enhance their effectiveness.
8. **Cultural Sensitivity in Legal Frameworks**: Explore how cultural values can be integrated into legal protections for indigenous knowledge to ensure that laws are respectful and reflective of community beliefs. Analyze how cultural sensitivity can enhance compliance and cooperation among stakeholders.