CHAPTER 1

Towards understanding the Framework and Historical Context for Protection of Biodiversity and Traditional Knowledge and redesigning Strategies towards Innovation

"A man can only attain knowledge with the help of those who possess it...One must learn from him who knows."

Georges Gurdjieff (1866-1949)

1.1 Introduction

The governance of Biological Diversity and Traditional Knowledge fall under the preview of International legal instruments that is oxymoronic. The focus of this study is on the assessment of International legal instruments that govern Biological Diversity and Traditional Knowledge specifically with reference to monopoly provided by Intellectual property Rights (IPRs) that refers to creations of individual mind that composing inventions, literary and artistic works, and symbols, names, images, and designs used in commerce, however another aspect refers to community creations that has evolved by transmission through communities through Traditional Knowledge evolution. There is a conflict in the international regime when creations arising out of genetic resources associated with traditional knowledge is considered prior art, hence not protectable for monopoly grants under IPR regime. The innovations and creative expressions of indigenous and local communities are also Intellectual property (IP), yet because they are “traditional” they may not be fully protected by existing IP systems. Access to, and equitable benefit-sharing in, genetic resources also raise IP questions. Indigenous and local communities justly cherish traditional knowledge (TK) as a part of their very cultural identities. Maintaining the distinct knowledge systems that give rise to TK can be vital for their future well-being.

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2 http://www.wipo.int/about-ip/en/ last accessed 4 May 2013
and sustainable development. TK can be inseparable from the ways of life of Traditional communities who are intrinsically linked with biological diversity and resources TK is developed as an intellectual response to the necessities of life. TK has also moved towards the centre of policy debate about Intellectual Property (IP). Various International treaties have come into force in the last two decades ranging from Convention on Biological Diversity (CBD), Trade Related Aspects of Intellectual Property Rights (TRIPS) of World Trade Organisation (WTO), Bonn Guidelines, International Union for Protection of Plant Varieties (UPOV), International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA), and Nagoya Protocol on Access and Benefit Sharing. New areas have cropped up specifically pertaining to access of Biological Resources and Traditional Knowledge associated along with benefit sharing from access converted to a product having association with communities holding and preserving knowledge through generations. Moreover tangible or non tangible information and biological resources need prior consent from the holders of knowledge if traditional knowledge is associated with it or even for accessing biological resources permission from National Biodiversity Authority (NBA) of countries with Material Transfer Agreements (MTA) has become the norm. With the changing scenario of International Regime some questions are raises that need an analysis

The Questions raised are:

- Can IPR bolster the cultural identity of indigenous and local communities, and give them greater say in the management and use of Biological Resources and TK to avoid misappropriation?
- What can be done to ensure that the interests of traditional communities holding information related to biological diversity and traditional knowledge is strategically used for Innovation? What kind of innovation in TK and GR would give communities the tools they need to safeguard their interests?

1.2 Summary of Prior art from literature

The review of prior art from literature takes the topic through the International Legal treaties in force. These treaties provide a framework for treating the subject with its provisions. The treaties have some conflicting provisions that would be reviewed. The
next part sneaks into how International treaties and IPR can be used to protect Genetic Resources and Traditional Knowledge. Traditional knowledge here is not restricted to Genetic resources but encompasses a wider dimension used by traditional communities on how intellectual creations of communities can be bought into the mainstream economics for enhancing livelihoods through strategic structural redesigning

1.3 International Legal Framework

A number of international treaties were negotiated for access to Biological Diversity and Traditional Knowledge namely, the Convention on Biological Diversity \(^3\) (CBD) in 1992 and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) in 1994 with the principles of Prior Informed Consent (PIC), and Access and Benefit Sharing (ABS) arising from the utilization of genetic resources and associated traditional knowledge. CBD uses the expression “innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity”. Biodiversity and Traditional Knowledge provide knowledge goods that can be aligned in a chain of innovation ending with a product. The CBD entered into force on 29 December 1993 with three main objectives of conservation of biological diversity, sustainable use of the components of biological diversity, fair and equitable sharing of the benefits arising out of the utilization of genetic resources. To date, CBD forms the most important convention on sustainable use of biodiversity and provides measures upon which bioprospecting could be regulated. The relationship between IPRs and the CBD tends to be treated as most relevant to the regulation of access to genetic resources and the development of measures to ensure fair and equitable benefit sharing with States and the holders of traditional knowledge. The CBD asserts the sovereign rights of nations over their national resources, and their right to determine access according to national legislation with the aim of facilitating the sustainable use of these resources, promoting access and their common use. It contains provisions which ensure that the genetic resources and knowledge associated with these cannot be treated as "free goods," and that there is a scope for each State

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party to frame regulations for controlling access to such resources in the interests of the national and local community. The most notable provisions of the Convention are Articles 8(j), 15, and 16. Article 8(j) provides the basis for the establishment of rights of the local communities over the biological resources of which they are custodians and the knowledge systems they have developed with regard to these resources. "Article 15 recognizes the sovereign rights of States over their natural resources and their authority to determine access to genetic resources and provides that access, where granted, shall be on mutually agreed terms and subject to prior informed consent of the provider party (contracting party)." Article 16, on access to and transfer of technology, requires parties to the Convention to undertake to provide and facilitate access and transfer of technologies to other parties under fair and most favourable terms. Article 16 is concerned with any technologies "that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment." Article 16.5 is more controversial, requiring the parties to co-operate to ensure that patents and other IPRs "are supportive of and do not run counter to" the CBD's objectives. This sparked severe disagreement during the negotiations between those who believed that IPRs conflict with the CBD's objectives, and others that saw no contradiction. However, terms such as "as far as possible" and "as appropriate" are vulnerable to being used by States as an excuse for non-action because of cited financial or other constraints of a similar nature. The CBD is believed to be more problematic because it does not contain "any compulsory provision for consent or participation of indigenous peoples in access to resources or knowledge. At the Sixth Session of the CBD Conference of the Parties (CoP-6) at The Hague in 2002, the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization were officially adopted to develop and implement effective and innovative mechanisms for access and benefit sharing. The Guidelines comprised a set of voluntary rules for drafting and progress of national biodiversity legislation and provided a framework to facilitate access and ensure benefit-sharing at national or regional levels. Further thereafter the Nagoya Protocol on Access to Genetic

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Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity⁵, an international agreement which aimed at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components, was adopted by the Conference of the Parties to the Convention on Biological Diversity at its tenth meeting on 29 October 2010 in Nagoya, Japan. Between CBD and Bonn Guidelines and Nagoya Protocol, emerged the most discussed WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS)⁶ on 1 January 1995 as a result of the Uruguay Round of multilateral trade negotiations covering areas of intellectual property, such as copyright and related rights, trademarks, geographical indications, patents including the protection of new varieties of plants, the layout designs of integrated circuits and undisclosed information including trade secrets and test data. With respect to patents, Article 27(1) of the Agreement defines the formal requirements regarding patentable subject matter and provides that patents shall be available for inventions that are “new, involve an inventive step and are capable of industrial application”. World Intellectual Property Organisation(WIPO)⁷ is an organisation that administers 23 international treaties dealing with different aspects of intellectual property protection and it counts 180 countries as Member States. Treaties of relevance to the international patent system are those of most

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⁵ Nagoya protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the convention on biological diversity.” In Secretariat of the Convention on Biological Diversity, Montreal. 2011. available at http://www.cbd.int/abs accessed May 2014

⁶ The Trade–Related Aspects of Intellectual Property Rights (TRIPS) Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994. The TRIPS Agreement, which came into effect on 1 January 1995, is to date the most comprehensive multilateral agreement on intellectual property with minimum standards of protection of Intellectual Property, with enforcement mechanisms Enforcement. through domestic procedures and remedies for the enforcement of intellectual property rights and dispute settlement mechanisms www.wto.org accessed March 2014

⁷ World Intellectual Property Organisation(WIPO) is one of the 17 specialized agencies of the United Nations, Convention Establishing the World Intellectual Property Organization was signed at Stockholm on July 14, 1967 as in Preamble, second paragraph, "to encourage creative activity, to promote the protection of intellectual property throughout the world" available at www.wipo.int accessed May 2014
relevance to the issue of access to genetic resources and benefit-sharing. WIPO formed the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("IGC") in 2001 as an international policy as a forum for debate and dialogue concerning the relationship between IP, and TK, genetic resources and traditional cultural expressions and establish a IPRs regime that could protect Genetic Resources, Traditional Knowledge and Folklore in line with CBD provisions and TRIPS Agreement Article 27.3(b). Though IGC's work has not produced any tangible results other than being a forum for discussion of legal, economic, and policy issues related to the protection of GRs and related TK, including the sui generis form of protection, it helped spark the awareness among the developing countries to safeguard their valuable knowledge assets. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO) provides minimum standards that Member countries agreed to, regarding protection of intellectual property. It came into effect at the end of the Uruguay Round of trade negotiations. These negotiations ended in 1995. The TRIPS Agreement addresses traditional concepts of intellectual property but does not address the protection of TK specifically. The Agreement excludes TK "by virtue of Article 70(3), which considers it as a part of the public domain." The relevant provisions in this regard could be Article 39 (protection of undisclosed information), if the TK is kept as secret knowledge, and Article 22 (protection of geographical indications). However, these Articles are of limited scope and application and fail to meet the concerns of developing countries. The issue of protection of TK was brought before the General Council of WTO, in the context of Article 27.3(b) of the TRIPS Agreement in 1999, which allows exclusion from patentability of plants and animals and essentially biological processes for their production, but obliges the protection of micro-organisms and micro-biological or non-biological processes for their production. These deliberations at the WTO Council for TRIPS clearly indicate that no appreciable achievement has been registered on the issue of legal protection of TK and that sharp differences exist between the member States, as it is observed that some countries seem to be more concerned with avoiding the misappropriation of traditional knowledge and with the implementation of the "sharing of benefits" principle than with the development of an intellectual property rights regime for traditional knowledge (most notably the U.S. and Japan). Others seem to aim at preserving the room existing at the national level to legislate on the matter. Out of 147
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parties to the TRIPS Agreement, three-fourths are developing countries, which are the chief holders of TK, and they want to correct the balance of TRIPS, which, according to them, is heavily tilted towards the interests of industrialized countries. Consequently, they have demanded the inclusion of TK in the TRIPS Agreement to get a fair return on their resources. The WTO may, however, be considered to be the most appropriate forum, with its dispute settlement mechanism and binding obligations and the procedure of negotiation.

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) was adopted by the Conference of the Food and Agriculture Organization of the United Nations (FAO) in November 2001, and entered into force on 29 June 2004. Currently, more than 71 countries have ratified the Treaty. This legally binding treaty covers all plant genetic resources for food and agriculture.

The objectives of the Treaty are “the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits derived from their use, in harmony with CBD, for sustainable agriculture and food security”. The treaty provides for benefit-sharing through the payment of monetary and other benefits of commercialization, information-exchange, access to and transfer of technology, and capacity building.

Traditionally patents were granted to protect inanimate inventions in chemistry, physics, electrical and mechanical fields. Two landmark court rulings in the European Court and US Supreme Court led to the extension of patent protection to life forms. The 1969 German Red Dove case\(^8\) ruling by the European Court that animal breeding technique by biotechnological methods were patentable and the 1980 USA Supreme

\(^8\) "The landmark decision for technicality in the field of biology was given by the German Supreme Court (BGH) in the case "Rote Taube" [6]. The red dove is a new race of doves as a result of selective breeding and crosses of already existing races. Although genetic crosses are biological processes, human selection has a technical aspect. The BGH concluded that a selective and systematic exploitation of natural forces including biological forces should not be excluded from patent protection. However, the pre-condition is its reproducibility which was not given in this case. This decision opened the way for patenting living matter in Europe. " as cited in Schütt, Corina. "Patents for biotechnological inventions." (2004) and German Supreme Court (BGH), decision of 27.03.1969 - X ZB 15/67 (BPatG).
Court in *Diamond v Chakrabarty*\(^9\) case ruling where a bacterium in which a plasmid from another strain had been inserted by Genetic Engineering techniques, were patented in the US. The US Supreme court held that ‘anything under the sun made by man’ was capable of patenting. Patenting under US law did not depend on whether the invention was living matter, but whether it was as a result of nature or made by human.

The Convention on International Trade in Endangered Species (CITES) of Wild Fauna and Flora entered into force in 1975 and now has 166 Parties. Its aim is to ensure that international trade in specimens of wild animals and plants does not threaten their survival. In order to do so, CITES regulates international trade in specimens of species of wild fauna and flora, including the export, re-export and import of live and dead animals and plants and of parts and derivatives thereof, based on a system of permits and certificates which can be used if certain conditions are met and that have to be presented before consignments of specimens are allowed to leave or enter a country. CITES does not address specifically the issue of access to genetic resources and benefit sharing.

However, in the context of discussions related to access and benefit-sharing, and more specifically of approaches to assist parties and stakeholders with the implementation of the access and benefit-sharing provisions of the Convention on Biological Diversity, it has been suggested that the permit system established by CITES to regulate the trade of endangered species could provide useful experience to draw from when examining the possibility of developing an international certificate of origin/source/legal provenance and the implications of such a certificate.

1.4 National Biodiversity Authority\(^{10}\) of India

India is one of the 12 mega biodiversity centres in the world. Like many other developing countries, India is at a crossroads with regard to the development of a new

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legal regime concerning the management of its vast biological resources and related knowledge. In pursuance of this, the Indian Parliament enacted the Biological Diversity Act 2002 in order to implement and give effect to the CBD. The Act was passed on February 5, 2003, and is an important step towards incorporating the CBD's policy framework at the national level, and was considered long overdue by various intellectuals and NGOs (non-governmental organizations) active in the field of IPRs and biodiversity conservation. Their demands and concerns were mainly spurred by the global hijack of Indian biodiversity and associated TK. Under § 36(5) of the Biological Diversity Act, it is provided that the Central Government shall endeavour to respect and protect the knowledge of local people relating to biological diversity through such measures as recommended by the National Biodiversity Authority (NBA). That could include registration of the According to § 3, persons who are not citizens of India, or associations or organizations which are not registered in India or which have non-Indian citizen participation in equity or management, would be prohibited from obtaining any biological resource originating within the country, and associated knowledge, without the prior approval of the National Authority. This prohibition is also applicable on citizens of India who live abroad. Some provisions are available to ensure monetary compensation to the providers of knowledge where the commercial exploitation of biological resources or knowledge was a result of access given by a specific individual or group of individuals.

1.5 Conflicts and Overlaps of International Agreements

Literature Review of the existing international provisions indicate that there are several gaps, loopholes, overlaps, and disconnects in the implementation of CBD and related Conventions. The relationship between the WTO-TRIPs Agreement and CBD on the scope of patent protection has been debated since 1999 but is yet to be concluded. CBD has been lauded by many developing countries as it recognizes the sovereign rights of nations over their resources. It recommends a fair and equitable benefit-sharing of resources and derived benefits between resource providers and users. It promotes the sharing of benefits derived from the use of genetic Resources. The Bonn Guidelines have given detailed mechanisms of how parties may develop their policies and legislations on access to biodiversity and benefit-sharing. This has formed the basis of many countries development of framework laws and policies on
biodiversity. The problem of CBD is on its generality in nature and lack of enforcement mechanisms. USA is one of the main users of biodiversity but has not ratified the Convention. Developed countries feel that CBD may not favour industrialized countries who are the leading consumer of the TK, and genetic resources. The main international instruments so far negotiated concerning biodiversity are: CBD, TRIPS and ITPGRFA. There are concerns that these international instruments on biodiversity and intellectual property had shortcomings, some provisions were ambiguous, incoherent and overlapping. It is important to understand the history behind the negotiations of these international treaties. The CBD negotiation under the auspices of UNEP, concluded in Rio de Janeiro, Brazil in 1992 was due to global concern on biodiversity degradation caused by human activities and the impact it had on our survival and livelihood. At around the same time, negotiation of TRIPS Agreement under WTO was going on in mid 1990s. The countries, in particular the US and the European countries felt that the developing countries were overriding on their protected technologies without payment of royalties and were getting unfair trade competition with counterfeits from developing countries, particularly in the US. The developed countries pressurized developing countries to enter into negotiation on TRIPS, because of the Dispute Settlement Mechanism within WTO system that would result in trade sanctions among WTO Members, unlike WIPO Treaties which did not provide for such mechanism. The two International Treaties, CBD and TRIPs were negotiated under different mandates and were bound to display some shortcomings, ambiguity, incoherence and overlaps. There are efforts, internationally through negotiations among the CBD Conference of Parties, WTO/TRIPS Council, and WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO-IGC), to harmonize the provisions on the shortcomings, ambiguity, incoherence and overlaps.

Agreement on Trade Related Aspects of Intellectual Property Rights provides private monopoly rights to individuals. Traditional Knowledge associated with Biodiversity, held by communities have experienced the test of time for centuries and transmitted orally from one generation to the other. Convention on Biological Diversity (CBD)  

recognizes sovereign rights of a Nation. To promote and safeguard access and equitable benefit sharing from Genetic resources having traditional value, the Nagoya Protocol was negotiated. Biological Diversity is defined as “the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part: this includes diversity within species, between species and of ecosystems”\(^\text{12}\). CBD does not confer protection for Biodiversity beyond National Jurisdiction, beyond 200 nautical miles, nor are these areas covered by Nagoya Protocol. With Bioprospecting avenues in high seas, Biodiversity has hidden potential and serves as a gold mine for new drug leads. At present, there are some 11,000 marine-derived natural products compared with more than 155,000 natural, terrestrial products\(^\text{13}\), showing marine derived natural products only contribute to 6.6% and terrestrial natural products constitute 93% of the natural products. The regulatory framework for access regime and modalities for benefit sharing from drugs discovered from biological resources of the high seas is unclear. Traditional knowledge refers to the content or substance of knowledge resulting from intellectual activity in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources\(^\text{14}\). Article 8j of CBD recognises innovations and practices of local communities limited to sustainable use and conservation of biological diversity and mandates Nations to promote with the approval and involvement of innovations and practices. It also mandates nations for equitable sharing of benefits arising from utilisation of innovations and traditional practices. Innovation happens between invention and revenue generation according to western concept. In steps between an idea or invention is protected through western form of protection through IP, it is then licensed or business plan is developed for production to enter market for revenue


\(^{14}\) WIPO (2007) Intergovernmental committee on intellectual property and genetic resources, traditional knowledge and folklore, the protection of traditional knowledge: revised objectives and principles, WIPO/GRTKF/IC/12/5(c) of 6 December 2007 WIPO.
generation. Underlying this concept to traditional knowledge seems difficult as western form of IP does not allow for protecting Traditional knowledge. CBD delves on the fact that traditional knowledge related to biodiversity can go through innovative process for economic gain. It leaves it to the Nations to enact legislations for promoting and protecting innovations of traditional communities. There is still a widespread tendency to regard traditional knowledge as unorganized and 'primitive' or as a treasure to store and document for posterity before it is lost, rather than seeing the dynamics that underpin the creation and dissemination of knowledge, in which local communities are key protagonists. Innovation is still often viewed as being mainly science led and created from the outside, and subsequently transferred to technology users, such as local communities, considered the recipients, of such innovation. In the present context Biodiversity and Traditional Knowledge have potential to be safeguarded through legal mechanism through already recognised as forms of Intellectual Property or new sui-generis mechanism for pulling leads for innovation for ultimate economic empowerment of communities.

### 1.6 Protection of Biodiversity, Traditional Knowledge and Intellectual Property Rights

The interplay between Intellectual Property Rights (IPR), Biodiversity (BD) and Traditional knowledge(TK) has been widely debated. Whereas IPRs are monopolistic individual private rights provided by law of the country on creative endeavour, TK and BD were considered as part of commons, freely assessable to mankind, like the space, air, deep sea oceans are all recognised as global commons heritage of mankind in international law. Convention on Biological Diversity (CBD) suppressed the notion of global commons and recognised sovereignty over natural resources. However it does not encompass Biodiversity that are beyond National Jurisdiction that have a huge potential for Bioprospecting for new drug leads. TRIPS is purportedly about trade related aspects of IP, but IP has many other aspects swept up by TRIPS including environment and biodiversity, indigenous rights, bioethics to name a few.

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most topical aspects of IP\textsuperscript{16}. All IP aspects are not trade related, including BD and TK. What kind of protection should be sought in such areas. Is TRIPS the only mandated legal way forward? What kind of innovations should be recognised by IP system\textsuperscript{17}. Are TRIPS and CBD consistent, or present fundamental conflict of international laws. The provisions of TRIPS don’t directly protect TK or BD, but it has several provisions that cover the subject matter eg. Article 15 for certification and collective marks to be used by indigenous and local communities, Article 22-23 pertains to GI for traditional product, Article 27 provides scope for excluding inventions based on TK or BD based on lack of novelty and inventiveness , Article 39 of TRIPS protects misuse of confidential information held by traditional communities\textsuperscript{18}. Should countries enact legislation in their territorial jurisdiction for protecting biodiversity and Traditional Knowledge which would be TRIPS –plus provisions. Countries like Brazil\textsuperscript{19}, China\textsuperscript{20}, Thailand\textsuperscript{21} and Philippine\textsuperscript{22} have already taken a step ahead for protecting medicinal products arising out of traditional practices by enacted legislations on TK related to medicines. These legislations can contribute towards a framework for model legislations at International and National Level for economic empowerment. Biodiversity and Traditional Knowledge have potential for economic empowerment if they are not seen through the lens of Western

\textsuperscript{16} Taubman, A. (2011). A practical guide to working with TRIPS. Oxford University Press. pg 5

\textsuperscript{17} Taubman, A. (2011). A practical guide to working with TRIPS. Oxford University Press. pg 185

\textsuperscript{18} Taubman, A. (2011). A practical guide to working with TRIPS. Oxford University Press. pg 187

\textsuperscript{19} Law No. 13.123 of May 20, 2015 (Access and Benefits Sharing of Genetic Resources and Associated Traditional Knowledge) entered into force November 17, 2015. The Law regulates access to components of the genetic heritage, protection of and access to associated traditional knowledge and the fair and equitable sharing of benefits for the conservation and sustainable use of Brazilian biodiversity. Available at http://www.wipo.int/wipolex/en/ maintained by WIPO. WIPO Lex facilitates public access to information concerning IP laws, regulations and treaties.

\textsuperscript{20} Regulation of April 2, 2003, of the People’s Republic of China on Traditional Chinese Medicines (promulgated by Order No. 374 of April 7, 2003 of the State Council of People’s Republic of China) entered into force on October 1, 2003. Available at Available at http://www.wipo.int/wipolex/en/ maintained by WIPO

\textsuperscript{21} The Protection and Promotion of Thai Traditional Medicine Intelligence Act B.E. 2542 (1999) enacted on November 19, 1999 contains provisions about Thai traditional medicine available at http://www.wipo.int/wipolex/en/ maintained by WIPO

\textsuperscript{22} Traditional and Alternative Medicine Act (TAMA) of 1997 (Republic Act No. 8423) and Executive Order No. 247 of May 18, 1995, prescribing Guidelines and establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By-Products and Derivatives, for Scientific and Commercial Purposes; and for other Purposes issued on May 18, 1995 available at http://www.wipo.int/wipolex/en/
IP rights. Are there possible alternatives for protection with IPR or beyond its realm. Is different treatment needed for protecting TK and BD? The research will analyse these questions in the present legal framework. Cases of misappropriation shall be analysed for their flaws and ways ahead for lessons to be learnt. Strategies shall be developed to extract Innovation out of traditional knowledge and biodiversity.

1.7 Review of literature

The review of literature takes the topic through the International Legal treaties in force. These treaties provide a framework for treating the subject within its provisions. Various International treaties have come into force in the last two decades ranging from CBD, WTO, TRIPS, Bonn Guidelines and Nagoya Protocol on Access and Benefit Sharing. The treaties have some conflicting provisions that would be reviewed. The review also sneaks into how IPR can be used to protect Genetic Resources and Traditional Knowledge. Traditional knowledge here is not restricted to Genetic resources but encompasses a wider dimension used by traditional communities. Finally review will be done on how intellectual creations of communities can be bought into the mainstream economics for economic empowerment.

Convention on Biological Diversity\(^{23}\)(CBD), 1992 came in force before much awaited TRIPS, as equity became the central plank in in law and policy on access to genetic resources and traditional knowledge with respect to conservation, development and human rights. The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), 1994 and CBD encapsulated the principles of Prior Informed Consent (PIC), mutually agreed terms and benefits sharing arising from the utilization of genetic resources and associated traditional knowledge. CBD uses expression to designate “innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity”. Biodiversity and Traditional Knowledge provide knowledge goods that can be aligned in a chain of innovation ending with a product. The CBD has three main objectives:

1) The conservation of biological diversity.

2) The sustainable use of the components of biological diversity.

3) The fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

To date, CBD forms the most important convention on sustainable use of biodiversity and provides measures upon which bioprospecting could be regulated. The relationship between IPRs and the CBD tends to be treated as most relevant to the regulation of access to genetic resources and the development of measures to ensure fair and equitable benefit sharing with States and the holders of traditional knowledge. The CBD asserts the sovereign rights of nations over their national resources, and their right to determine access according to national legislation with the aim of facilitating the sustainable use of these resources, promoting access and their common use. It contains provisions which ensure that the genetic resources and knowledge associated with these cannot be treated as "free goods," and that there is a scope for each State party to frame regulations for controlling access to such resources in the interests of the national and local community. The most notable provisions of the Convention are Articles 8(j), 15, and 16. Article 8(j) provides the basis for the establishment of rights of the local communities over the biological resources of which they are custodians and the knowledge systems they have developed with regard to these resources. "Article 15 recognizes the sovereign rights of States over their natural resources and their authority to determine access to genetic resources and provides that access, where granted, shall be on mutually agreed terms and subject to prior informed consent of the provider party (contracting party)." Article 16, on access to and transfer of technology, requires parties to the Convention to undertake to provide and facilitate access and transfer of technologies to other parties under fair and most favourable terms. Article 16 is concerned with any technologies "that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment." Article 16.5 is more controversial, requiring the parties to co-operate to ensure that patents and other IPRs "are supportive of and do not run counter to" the CBD's objectives. This has sparked severe disagreement during the negotiations between those who believed that IPRs conflict with the CBD's objectives, and others who saw no
contradiction. However, terms such as "as far as possible" and "as appropriate" are vulnerable to being used by States as an excuse for non-action because of cited financial or other constraints of a similar nature. The CBD is believed to be more problematic because it does not contain "any explicit requirement for the consent or participation of indigenous peoples in access to resources or knowledge."

1.7.1 The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing\(^\text{24}\) of the Benefits Arising out of their Utilization were officially adopted in 2002 at Sixth Session of the CBD Conference of the Parties (CoP-6) at The Hague. The Guidelines consist of a set of voluntary rules to assist in the drafting and progress of national biodiversity legislation or administrative regulation, by providing "a transparent framework to facilitate access and ensure benefit-sharing at national or regional levels

1.7.2 The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity\(^\text{25}\) was aimed at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components. It was adopted by the Conference of the Parties to the Convention on Biological Diversity at its tenth meeting on 29 October 2010 in Nagoya, Japan.


\(^{25}\) Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, Nagoya, 29 October 2010, available at https://www.cbd.int/cop/ (accessed 20 December 2015). The Conference of the Parties to the Convention on Biological Diversity (COP - CBD) during Tenth meeting at Nagoya, Japan, 18-29 October 2010 in Agenda item 3 on decision adopted by the Conference of the Parties to the Convention on Biological Diversity at its tenth meeting X/1 on Access to genetic resources and the fair and equitable sharing of benefits arising from their utilization decides to adopt the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (the Protocol) as set out in annex I to the present decision The Protocol is available at http://www.cbd.int/abs
1.7.3 The WTO Agreement on Trade Related Aspects of Intellectual Property Rights (WTO-TRIPS)\textsuperscript{26} The TRIPs Agreement came into force on 1 January 1995 as a result of the Uruguay Round of multilateral trade negotiations. It covers trade related areas of intellectual property, such as copyright and related rights, trademarks, geographical indications, patents including the protection of new varieties of plants, the layout designs of integrated circuits and undisclosed information including trade secrets and test data. With respect to patents, article 27(1) of the Agreement defines the formal requirements regarding patentable subject matter and provides that patents shall be available for inventions that are “new, involve an inventive step and are capable of industrial application”.

1.7.4 World Intellectual Property Organisation (WIPO)\textsuperscript{27} started to work on TK in 1998 with some 3,000 representatives of TK-holding communities in sixty locations around the world. In 2001 WIPO established an Intergovernmental Committee known as The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO-IGC) to respond to Members’ request to establish a IPRs regime that could protect Genetic Resources, Traditional Knowledge and Folklore in line with CBD provisions and TRIPS Agreement Article 27.3(b). The WIPO-IGC is currently involved in discussions on a number of issues such as: i. considering intellectual property issues that arise in the context of access to genetic resources and benefit sharing, the protection of traditional knowledge, innovations and creativity, and the protection of folklore; ii. reviewing clauses related to IPs in access and benefit-sharing; and iii. working to devise a format for an electronic database of contract clauses and practices concerning access to genetic resources and benefit-sharing. The Member States after IGC deliberations have agreed that WIPO should produce the elements for a model \textit{sui generis} system of protection for TK, though the developed countries stress that any legally binding international \textit{sui generis} system at this stage is premature and unnecessary and that such attempts should first be made at the national level to determine feasibility. Generally speaking, while the IGC's work has not produced any tangible results other than being a forum for discussion of legal, economic, and policy issues related to the protection of GRs and related TK, including the \textit{sui generis} form of protection, it

\textsuperscript{26} www.wto.org (accessed 20 December 2015)
\textsuperscript{27} www.wipo.int (accessed 20 December 2015)
helped spark the awareness among the developing countries to safeguard their valuable knowledge assets.

1.7.5 TRIPS, Traditional Knowledge, and Genetic Resources

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO) provides minimum standards that Member countries agreed to, regarding protection of intellectual property. It came into effect at the end of the Uruguay Round of trade negotiations. These negotiations ended in 1995. The TRIPS Agreement addresses traditional concepts of intellectual property but does not address the protection of TK specifically. The Agreement excludes TK "by virtue of Article 70(3), which considers it as a part of the public domain." The relevant provisions in this regard could be Article 39 (protection of undisclosed information), if the TK is kept as secret knowledge, and Article 22 (protection of geographical indications). However, these Articles are of limited scope and application and fail to meet the concerns of developing countries. The issue of protection of TK was brought before the General Council of WTO, in the context of Article 27.3(b) of the TRIPS Agreement in 1999, which allows exclusion from patentability of plants and animals and essentially biological processes for their production, but obliges the protection of micro-organisms and micro-biological or non-biological processes for their production. These deliberations at the WTO Council for TRIPS clearly indicate that no appreciable achievement has been registered on the issue of legal protection of TK and that sharp differences exist between the member States, as it is observed that some countries seem to be more concerned with avoiding the misappropriation of traditional knowledge and with the implementation of the "sharing of benefits" principle than with the development of an intellectual property rights regime for traditional knowledge (most notably the U.S. and Japan). Others seem to aim at preserving the room existing at the national level to legislate on the matter. Out of 147 parties to the TRIPS Agreement, three-fourths are developing countries, which are the chief holders of TK, and they want to correct the balance of TRIPS, which, according to them, is heavily tilted towards the interests of industrialized countries. Consequently, they have demanded the inclusion of TK in the TRIPS Agreement to get a fair return on their resources. The WTO may, however, be considered to be the most appropriate forum, with its dispute settlement mechanism and binding obligations and the procedure of negotiation. Recent
negotiations at WTO in 2013 have allowed for 5 years more relaxation for Least Developed Countries to abide with TRIPS enablement.

1.7.6 International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

Traditionally patents were granted to protect inanimate inventions in chemistry, physics, electrical and mechanical fields. Two landmark court rulings in the European Court and US Supreme Court led to the extension of patent protection to life forms. The 1969 German Red Dove case ruling by the European Court that animal breeding technique by biotechnological methods were patentable and the 1980 USA Supreme Court in Diamond v Chakrabarty case ruling where a bacterium in which a plasmid from another strain had been inserted by Genetic Engineering techniques, were patented in the US. The US Supreme court held that ‘anything under the sun made by man’ was capable of patenting. Patenting under US law did not depend on whether the invention was living matter, but whether it was as a result of nature or made by human. The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) was adopted by the Conference of the Food and Agriculture Organization of the United Nations (FAO) in November 2001, and entered into force on 29 June 2004. This legally binding treaty covers all plant genetic resources for food and agriculture. Its objectives are “the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits derived from their use, in harmony with CBD, for sustainable agriculture and food security”. The treaty provides for benefit-sharing through the payment of monetary and other benefits of commercialization, information-exchange, access to and transfer of technology, and capacity building.

1.7.7 The Convention on International Trade in Endangered Species (CITES) of Wild Fauna and Flora entered into force in 1975 and now has 166 Parties. Its aim is to ensure that international trade in specimens of wild animals and plants does not threaten their survival. CITES regulates international trade in specimens of species of wild fauna and flora, including the export, re-export and import of live and dead animals and plants and of parts and derivatives thereof, based on a system of permits and certificates which can be used if certain conditions are met and that have to be presented before consignments of specimens are allowed to leave or enter a country.
CITES does not address specifically the issue of access to genetic resources and benefit sharing. However, in the context of access and benefit-sharing issues and more specifically of approaches to assist parties and stakeholders with the implementation of the access and benefit-sharing provisions of the Convention on Biological Diversity, the permit system established by CITES to regulate the trade of endangered species could provide useful experience to draw from when examining the possibility of developing an international certificate of origin/source/legal provenance and the implications of such a certificate.

1.7.8 Review of Articles

Paul Kuruk\(^{28}\) studies cases relating to customary laws used by traditional communities who after pressures have embarked on measures to enhance the protection of indigenous and traditional knowledge. In *Foster v. Mountford*, an indigenous group prevailed in its breach of confidence claim against an anthropologist planning to publish a book containing information he received from tribal leaders about tribal sites, objects, communal legends, secrets, paintings, engravings, drawings, and totemic geography. Similarly, in New Zealand, the recognition of customary law has been characterized as "very limited and constricting, treating Maori customary law as analogous to foreign law or local custom in England. The study concerns with the bargaining power of Traditional communities.

Paul Kuruk\(^{29}\) studies misappropriation of traditional knowledge. He analyses by reflecting on the deep suspicions of the U.S. government that a stronger recognition of traditional knowledge could be used politically by Indian groups to press for rights of self-determination and greater autonomy from the federal government, no provision is made under domestic law for protecting traditional knowledge outside the limited parameters of cultural heritage legislation and the limited jurisdiction of Indian tribal courts.

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Yousaf Ishaq Khan\textsuperscript{30} points out several shortcomings from both the regulatory and enforcement viewpoints of National Biodiversity Authority that establishes a regulatory and enforcement mechanism within India. Practically, it does not provide effective measures for the protection of genetic resources and related TK and is heavily biased against the interests of tribal and local communities who are the original guardians of the associated knowledge.

Gregory K. Schlais\textsuperscript{31} examines the issues surrounding the taro patent controversy in Hawai\textprime. Opponents of the patenting of kalo, or taro, tore up copies of the plant patents on the new hybridized varieties of the Native Hawaiian people's staple, symbolizing that no entity or person owned the sacred plant. In essence, the taro patent controversy goes to the root of the collision between IPRs and traditional knowledge and cultural heritage. Since the patenting of taro is shown as a case example of how tension among western ideologies of IP clash with traditional knowledge and cultural heritage.

Patrick Marten,\textsuperscript{32} focuses on International Economic Law concerning Geographical Indications and TK for developing countries; the intention is to explore firstly whether GIs can be used to protect traditional products; secondly whether GIs are indeed the best way forward in the light of increasing use of regional legal frameworks and \textit{sui generis} measures; and finally how the legal measures and legal frameworks can positively impact on economic development enhance the livelihoods of TK/GR holders and communities.

Anil K Gupta\textsuperscript{33} provides primary information on Grassroot Innovations through Shodh Yatras to recognise, respect and reward the creative communities and individuals at grassroots in rural and urban areas through Society for Research and Initiatives for Sustainable Technologies and Institutions (SRISTI) and Honey Bee

\textsuperscript{32} Martens, Patrick. "Can Traditional Knowledge Owners and Producers in Developing Countries Use Geographical Indications for Protection and Economic Development Gain?." (2012).
Network and National Innovation Foundation (NIF) for about two decades. The study focuses on actual users of TK and important for my area of research to incorporate actual examples form India and compare it with the innovative ecology of other countries. The work provides a preliminary enquiry on documentation. It lacks the steps forward for promoting Entrepreneurship among TK holders for taking the knowledge embedded in products to the market. The report lacks strategy for diffusion of grassroots innovations collected from holders of knowledge. Mere collection of information with Prior Informed Consent does not provide a platform to the knowledge holders without entrepreneurship support. This issue of diffusion of innovation for traditional communities will be worked with possible innovative solutions for upscaling for vertical and horizontal growth.

David R Downes\(^{34}\) explores the option of using geographical indications and trademarks to create market incentives for local and indigenous communities to produce traditional products based on their knowledge of sustainable uses of biological resources. Another involves the possible creation of non-market rights for indigenous and local communities to protect their traditional knowledge, looking to precedent in the European concept of the author's moral rights. The study is more suggestive with a theoretical framework. It lacks practical applicability. The different options of protection provided makes this article an important source for debating issues like Moral right protection for Traditional knowledge to be embedded in TRIPS.

Gurdial Singh Nijar\(^{35}\) identifies the key issues that need to be considered and resolved for TK associated to genetic resources to form an integral and viable component of the proposed international regime. This article has outlined the problems and prospects in incorporating associated TK into a prospective international regime.


María Costanza and Julie Laplante 36 focus on how local communities, in a network of supportive partnerships, draw knowledge for others, combine it with their own knowledge and then innovate in their local practices. The case studies analyzed highlight the need to link local communities to other social and economic agents whose capabilities are necessary for many substantive innovation processes to take place. Due to unequal power relations, innovation may also have negative effects, such as the transformation of these traditions into knowledge that is unrecognizable and difficult to integrate in local practices. Innovation may also lead to the transformation of these healing traditions into health commodities controlled by new elites. This paper specifically deals with health practitioners and their knowledge. Moreover, the data collection was done for a period of only four months, by outsiders. It also points out ethical issues of surveying and publishing.

Graham Dutfield 37 underlines the opportunities and challenges proposed for protection of TK and TCEs, that are now being discussed in so many different international forums. Unfortunately, historical and present day practices justify some anxiety including a feeling that for many countries, the prior informed consent to be sought must come from a government body only, and not from traditional communities at all, it is possible that the biggest achievement will be an international declaration, resolution or code of conduct. The study provides for National regimes to overtake and address issues of Traditional communities.

Evanson Chege Kamau, Bevis Fedder and Gerd Winter 38 examine the Nagoya Protocol that constituted the latest ambitious approach to develop an international instrument complementing critical aspects of previous ABS instruments. Considering positive and negative features, the Protocol probably reflects what could be reached at all given the clash of interests behind it. The actual utility of the Protocol will only become visible during the implementation phase. India has ratified

the Nagoya Protocol, it is now on the Soverieginity of the Nation on how best it can use the provisions of Access and Benefit sharing of TK and GR. India could only propose a weak draft that yet needs scrutiny.

**Kabir Bavikatte and Daniel F. Robinson** discuss about Biocultural Jurispudence and Biocultural Rights of property and its nature of being universally commensurable, commodifiable and alienable. Little or no effort has been made to consolidate this biocultural jurisprudence into a body of knowledge relating to biocultural rights that can be effectively used and implemented by the very indigenous peoples and local communities who struggled for it and whose interests these rights seek to defend. The paper discusses a new theory of Biocultural jurisprudence that would encompass all rights collectively by the Traditional knowledge holders. This provides an interesting angle to protection of GR and TK.

**Peter Johan Schei and Morten Walløe Tvedt** aim at contributing to the development of an International Regime on Access and Benefit Sharing (ABS) by clarifying the concept of ‘genetic resources’ as it has emerged and keeps evolving - particularly in light of the new knowledge and understanding developed in genomics and proteomics. An International ABS Regime could maintain a broad and dynamic understanding of the concept of genetic resources. The paper discusses a dilemma and a contradiction between on the one hand leaving a definition dynamic and flexible, at the same time as it is understood in a manner which creates legal certainty and thus is enforceable.

**Maxim V. Gubarev** discusses the issue of patenting traditional knowledge and genetic resources, as well as all innovations deriving from them, presents a difficult problem compromising of legal, economic, public and moral considerations.

**Jane Anderson** explores the relationship between indigenous/traditional knowledge and intellectual property law as a complicated contemporary legal

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problem. Indigenous peoples do not necessarily interpret or conceptualize their knowledge systems and knowledge practices in the same way or only through these concepts. While the value of indigenous knowledge has changed dramatically in the last ten years, there is not yet an international consensus about how indigenous rights to the protection of their knowledge systems can be secured, either within an intellectual property regime or through some other over-arching legislative or policy framework. Rethinking how we do research, how we conceptualize knowledge, how we share knowledge, how we recognize legitimate overlaps in knowledge use and circulation, and the extent of the role of law in influencing our social orders of knowledge exchange, are necessary starting points.

1.7.9 Review of Books

The origins of IP protection can be traced back to 4th century BC where in Aristotle’s *Politics*, the use of the term Monopoly is used. Evanson and Gerd theoretically reflect on the concept of Justice underlying access and benefit sharing focussing on Traditional knowledge related to Genetic Resources. The logic of *iustitia distributiva* and *iustitia commutativa* is discussed to govern national and multilateral measures for decision making. An interesting point is taken up for discussion on marine genetic resources. It raises a question that CBD does not apply to genetic resources of deep seabed beyond the outer edge of continental shelf. Some reflections are made on UN Convention on Law of Seas (UNCLOS). The book proposes a code of conduct for researchers who disseminate traditional knowledge and bring it to public domain. It also proposes to sensitize indigenous communities on demanding official permit to bio-prospectors. This book does not cover aspects of traditional knowledge not related to Genetic resources. My interest is also to encompass protection for other forms of traditional knowledge. This book covers a part of the subject area of my topic.

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43 Aristotle, Politics 350 BCE, also available at http://classics.mit.edu/aristotle/politics.1.one.html (accessed 3 May 2013)
Christoph Antons\textsuperscript{45} highlights the international debate about traditional knowledge, traditional cultural expressions and their relationship to IPR in the Asia-Pacific region. Customary law of Australia has been discussed that provides limited common property law. Case studies have been included from India and Phillipines. Indonesia recognises community intellectual rights. Protection of TK has been attempted via a diverse Controversial use of Maori words use by characters of Lego game was manufactured by Sony. In the story line Maori myth, clan systems and rituals were used. After complains from Maori community Lego agreed to refrain from sensitive words and agreed to develop a Code of Conduct for use of culturally sensitive material on its toys. Culturally inappropriate representations of designs, sacred stories were used on the website of two American Didgeridoo players. After several complaints by Arnhem land clan groups, the material was taken down and letter of apology posted on the website. Indian Traditional Knowledge Digital Library (TKDL) and Indonesian Jamu industry has also been discussed. The book provides an important framework with latest case studies in a holistic approach. The book emphasises on protection than on providing solutions for community empowerment through livelihood gains.

Julia Honds\textsuperscript{46}, provides an overview of the problems and issues that arise when Traditional Knowledge meets the Western intellectual property regime. The chapters provide examples of misappropriation of the knowledge shared by San Tribe regarding Hoodia Gordonii Cactus. The traditional knowledge is of immense value to the pharmaceutical companies, they seek raw information as leads to further explore that knowledge, which otherwise in the lab may take many years of toil and investment in dollars. The author recommends protection of traditional knowledge by a sui generis law specially designed for the purpose, which will seek to balance conflicting interests of western intellectual property law. This book supports the concept of sui generis form of IPR for traditional knowledge.


\textsuperscript{46} Honds, Julia. The protection of traditional indigenous knowledge by intellectual property law. GRIN Verlag, 2008.
Johanna Gibson, discusses that the protection of traditional knowledge through patenting is unlikely because of the problems associated with fulfilling requirements of novelty and inventiveness but patenting of material derived from traditional knowledge in medicines and plants is possible by virtue of failure to fulfil these same criteria. The numerous international instruments distil the concerns of indigenous and traditional communities with the international context of development, efficiency and trade. Assimilating TK, folklore and genetic resources within an international intellectual property law is rejected as the IP model is incoherent and unjust. IP is shown to operate as a grand narrative for innovation rendering international trade more efficient, from the authors viewpoint it is more of antisocial and senseless. The exclusion of Article 9 of TRIPS was justified at first by the developed countries, on the basis that moral rights are not trade related. Protection of traditional knowledge and resources is of critical concern not only to the groups involved but also to the international trading community for which these resources are of increasing economic importance. An interesting dimension is the removal of 6bis from Berne included in TRIPS. The author critically examines the cultural and philosophical underpinnings of current legal practice which is of interest to my research topic and provides food for thought with facts and figures.

Riley in the book emphasises on the legal obstacles and innovative solution like copyright collectives laid in legal framework for protecting indigenous intellectual property rights. The Bulun-Bulun case in Austraila is discussed. Similarly silver hand a trademark of the Alaska community is discussed, for native arts and crafts, and the trademark is inherited by the artist of the community. A landmark law passed by Panama in June 2000 grants collective and perpetual copyright over indigenous artistic creations- including art design, music, performance and dress. The concept of collective trademark is also taking shape. Australia allows for “indigenous creator” and label of authencity for aboriginal artist. Collaboration mark is also used. Trademarks work well and the symbols have the power to mark identity and denote

authenticity. In a landmark case in late 1994, a Federal Court in Australia awarded more than $145,500 in copyright infringement to Aboriginal artists whose designs were made into carpets in Vietnam and sold in Australia for $3,000 per piece. However in another case, after the thunderbird design on Cowichan sweaters was mass produced at profits of millions of dollars, the Cannadian First Nation filed suit. The settlement required removal of the name Cowichan from products, but since the design had been in public domain, it was ruled that the tribe did not have standing to receive compensation for use of design. This has been the fate of most ethnographic objects and designs created by unnamed artists, held by museums, exiting in public domain, unprotected by copyright. The study explores legal strategies for defending the artistic and technological creations of indigenous peoples from misuse by outsiders and provides a different facet for my research topic.

Erbisch and Maredia⁴⁹, have updated IPR prevailing in the core area of agricultural Biotechnology. They discuss about the agricultural germplasm exchanges that comes from the developing nations like Maize was domesticated in Mexico, tomato and potato in Andes. Out of selective breeding of these in developed countries hybrids emerged. The wild relatives and landraces are of interest to the plant breeder to incorporate resistance and incorporate adaptability from abiotic stress. Regional case studies have been incorporated from Egypt, South Africa, Australia, China, Russia, Andean Pact Countries of Latin America, Costa Rica, European Union, Indonesia, Brazil and India. The case studies shall serve as secondary sources for area in agricultural genetic resource exchanges and need of developed countries for enhanced access accruing to hybrid fatigue and improvement of germplasm.

Susette and Thomas⁵⁰, discuss that prevailing legal instruments in International agricultural, environmental and trade law are not sufficient to preserve biodiversity and improve sustenance farming for large parts of globes rural population. The book is limited to TK related to plant genetic resources only. It encompasses knowledge of

farming communities around the world. The book does not include TK relating to cultural diversity in a broad sense. They propose a *sui generis* IP known as TIP Rights (Traditional Intellectual Property Rights) to take care of the unfair competition by providing legal security relating to plant genetic resources. Legislations of India, Australia, Peru, Europe, USA, Australia have been discussed for protection of TK related to plant varieties. Case studies of misappropriation of Turmeric patent, Basmati, Neem (*Azadirachta indica*) patent and Kava case Ayahuasca (*Banisteriopsis caapi*), Quinoa (*Chenopodium quinoa*), Phyllanthus amarus used for jaundice in ayurveda and Kava (*Piper mythesticum*) of the Pacific, where it is highly valued as source of ceremonial beverage. More than hundreds of varieties of kava are grown in pacific. French company L Oreal has patented the use of kava to reduce hair loss and stimulate hair growth. Successful cases of benefit sharing include Hoodia (*Hoodia gordonii*) is discussed.

Jonathan Curci\(^{51}\) discusses about the protection of traditional Knowledge and biodiversity in the light of intellectual property rights. Various defensive and positive protection measures are discussed like, certificate of disclosure, protecting Traditional knowledge through Article 27.3(b) of TRIPS, utilising Geographical indications and trade secrets. Analysis of contractual provisions is made with a *sui generis* IP system with liability for misappropriation. This book fills the gap by covering areas of Access and benefit sharing by contractual provisions and through CBD, that gives a fresh insight for existing case studies for comparison and hence selected for review for my research topic.

Tania Bubela & Richard Gold\(^{52}\) describe and define protection of Traditional knowledge nationally and internationally. The authors use a new term Associated Traditional knowledge (ATK). The implementation and effect of rights of indigenous people of four jurisdictions viz Brazil, Kenya, India and Canada is studied. The four jurisdictions provide opportunity to compare effect of laws based on property rights. Barcoding of life project is discussed. Nagoya Protocol and Bonn guidelines arising out of CBD are discussed. Potential of GI is also discussed. It fills the gap by

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incorporating Nagoya protocol and case studies from four countries for a comparative approach to learn lessons from other countries, hence apt for research topic.

Terri Janke\textsuperscript{53} discusses eight case studies related to indigenous works, designs, and trademarks. Protection of culture by registration has been put forth as a suggestion. Prior informed consent can also be applied for stories, and cultural events documentation by third parties. Certification marks usage is also discussed with unauthorised reproduction and proper marketing. This Book serves as a good reference material to study cases of traditional communities. Though the cases occurred in the year 2000, their relevance still exists, and further incorporations will be done of latest developments. Though the book does not discuss about genetic resources, the traditional knowledge of communities case studies provide immense information as a starting point for comparison for proposed research area.

J Michael and Philip Schuler\textsuperscript{54} explain about the finalisation of Uruguay round of agreement in 1995 and subsequent enactment of TRIPS, that for developing counties was paying for technology of developed countries. The case study on Yekuana tribals teach lessons from their experience, on how they strengthened their weak disordered indigenous culture that had scattered, now is in interface with the modern world. The case study of India deals with the problems artisans are facing. An example is cited of Kerala boat that is now used for high end tourism showcases that uniqueness of traditional knowledge can be exploited for entrepreneurship and economic livelihood of the artisanal community. Indian artisans too face the problem of cheap knockoffs, extensive copying, buyers buy sample of design and bulk manufacture somewhere else. Fair trade provisions help in commercialising traditional crafts and is also a means to stop misappropriation. Empowerment of poor musicians is also discussed. Piracy is also rampant in the design sector where designers take inspiration from local artisans and protect in their territories. Cases of basmati, turmeric and Enola are discussed. Also Kani tribe access and benefit sharing regime is considered as the best model, however it needs evaluation as to whether benefits were sustainable in the long run, or just enacted to comply with CBD objectives. The case of Pueblo of Santo

Domingo is discusses where tribals filed infringement suit against a newspaper that published it, which had to be kept secret according to customary law alleging trespass and invasion of privacy. This book provides cases from the globe for comparision. It provides novel insights to the protection of traditional crafts and rituals, and proposes benefit sharing mechanism based on commercial gains, hence this book is relevant for my research topic on traditional knowledge.

Sarah A A Laird\textsuperscript{55} analyses facts and figures and case studies related to traditional knowledge and intellectual property rights. The book is on tinkering and enhancing the process of protection. The book seeks to examine ways that current and future activist may equate with fairness and equity. It fills the gap of lack of practical information available on equitable biodiversity research and prospecting partnerships. The book also examines biodiversity prospecting contractual agreements, the minimum standards needed, and decisions related to prior informed consent. A biodiversity trust fund is deliberated upon. This book provides a comprehensive guideline for researchers and academicians, it also provides insight into best practices with comparision across the globe.

Tobias Kiene\textsuperscript{56}, discusses about the legal protection that needs to be accorded for traditional knowledge providing leads for new molecule in pharmaceutical field. The controversial patents on \textit{Catharanthus roseus, Curcuma Longa, Arogyapaacha, Hooda gordonii, Homalanthus nutans} and \textit{Phyllanthus niruri} derived from traditional knowledge are discussed. There is no legitimacy behind imposing patent system on communities who don’t accept it as it is contrary to their basic customary premises, where knowledge is shared among community. The bio- prospecting team goes in the field for collection with local communities, identify a plant, leading to extraction of active biomolecule. Patenting truncates the entire social network who were involved in the discovery process. Not a single example has come up where a patentee has given the name of the tribesmen in patent application, or acknowledged it. They call the process of extraction as novel. The legal system sets in artificial boundaries. The IP system needs a law that can safeguard indigenous communities against violation


of their rights. This book provides case studies of biopiracy in the pharmaceutical sector. My research area touches the issue of misappropriation and the cases in the book will give me a lead to evolve best practices in case of infringing.

Till date only 5 % of worlds biodiversity has been screened for the presence of bioactive compounds. 40 % of US prescription drugs and 63% of all anti cancer drugs are based on natural products Natalie Stoianoff\(^57\) portrays the view of a researcher during access of Biological material for bioprospecting. Compounds like Mevacor, used for reducing cholesterol levels by Merck has annual sales of USD 700 million. Similarly, Vinblastine, Vincristine, Taxol, Artemisinin, Reserpine, all owe their extraction from plant sources. The author also informs about a few cases where biological resources were extracted from oceans that did not belong to a country. In other cases, Merck procured entire flora and fauna of Coata Rica and paid 1.135million USD upfront. The author discusses the importance of natural resources from scientific perspectives and provides solutions to have international treaty for any kind of excavation. The book provides trajectories from the scientific world, and the relationship of conservation of biological resources for ethnobotany, biocommunity and biodiversity, hence important for my research area, though the focus is mostly Australian in reflection. An important area touched by the author related to bioprospecting from marine genetic resources that are under Areas beyond National Jurisdiction that are beyond the scope of CBD and Nagoya Protocol. Bioprospecting of genetic resources from no mans territory is a dimension that needs International law for harmonisation is an area that needs policy guidelines.

Jane E. Anderson\(^58\) book focuses on Australia region, it illuminates how politcial, economic and cultural issues revolve around securing ip rights in Indeginous knowledge. Cases of impact namely 1983 case of an Yanggarny, an aboriginal artist of Australia who commenced copyright infringement against a retailer who copied designs on clothes without the artists consent. Another land mark case \textit{Melpurrurru & others v Indofurn Pty Ltd}, involving unauthorised reproduction of aboriginal artists work on carpets. In both the cases the IP of Abroginal artists were legally secured.


These two cases show how western legal framework can protect the interest of Indigenous communities. Discussion is made on how IP can be used to secure monopoly of indigenous community rights for control and access. The work proposes to reframe and rethink about the wordings in International treaties and use it for protecting Aboriginal artists. This Book is relevant for my area of work as I shall also deal with traditional culture that has designs, folklore, music and other grey areas that have a potential for protection through copyright and developing collective societies.

Lewinski and Hahn\(^{59}\) study the grey areas in the book with reference to Traditional knowledge and IP. Though the limitation of this study is that it can hardly do any justice to the entire topic from indigenous point of view. The authors have shelved TK, GR and folklore in existing frame work of IP and International law. An insight is provided into the problematic areas of customary law, objections to *suigeneris* protection, usefulness of databases and collecting societies in the same norms as of Copyright societies. The Book provides interesting vision for developing on existing framework with innovative solutions.

Ikechi Mgbeoji\(^{60}\) discusses misappropriation cases of Insect resistant Cowpea of Nigeria, Chickpea of India and Iran, Quinoa of Bolivia, Ricetech patent for basmati, whose claims 8 ,9 and 11 still stand. He also examines “Common Heritage of Mankind” theory as an accepted part of International Law. He discusses about International Agricultural Research Centres (IARC), involved in the exchanges and ex-situ collection of PGR. Traditional Knowledge Uses of Plants (TKUP) has become a debating issue in international arena where folk knowledge is devaluated and characterised as inferior. This book provides competing philosophical theories that have had an impact on international treaties. My area of research would dwelve on those theories as a ground substance for purporting a new paradigm for protecting traditional knowledge.


Chidi Oguamanam focuses on North South Relations on aspects related to Intellectual property and builds community common rights for changed IP scenario and discusses case examples from biotechnology, biodiversity, bioprospecting and biopiracy, warranting for protection in International law jurisprudence. My area of work focuses on models of governance of IP for traditional knowledge holders, hence this book is apt for a comparative approach of Developed countries with Developing countries for traditional knowledge protection.

1.8 Objective of Research

The Objectives of proposed research are:

- To analyse the governance of existing International legal instruments for governance of Biodiversity and Traditional Knowledge in territorial and non territorial jurisdiction
- To recommend future strategies to promote innovation arising out of Biodiversity and Traditional Knowledge to empower traditional knowledge holders

Hypothesis and Research Questions

Hypothesis

*The International Legal Instruments are not sufficient to protect Biodiversity and Traditional Knowledge. However it is possible to come to a conclusion in future if the coherent efforts are made*

Research Questions

1. What are the legal instruments governing protection of biodiversity in territorial and non territorial jurisdiction and what are the challenges?
2. What are the issues in bioprospecting related to Marine Genetic Resource (MGR) in Areas Beyond National Jurisdiction (ABNJ) that are beyond the scope of Nagoya Protocol and CBD? What is the existing relationship among TRIPS,

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CBD and ITPGRFA in view of governance and access and benefit sharing of Biodiversity and associated Traditional knowledge?

3. What are the existing patents related to Biodiversity and Traditional Knowledge for bioactive compounds?

4. How can TK and BD be strategically used to cater towards innovation for empowerment of traditional knowledge holders?

1.9 Significance of Study

The study aspires to contribute to the body of substantial knowledge of Biodiversity and Traditional Knowledge in present scenario of interwoven legal regime. Available literature throws some light on protection not on innovation. The study will show future directions by mapping future strategies for innovation by converting Biodiversity and Traditional Knowledge into tangible products for economic empowerment of communities.

1.10 Research Methodology and Scope of Study

A Combination of doctrinal, comparative and interdisciplinary methods of legal research, review of existing laws, national and international treaties and jurisprudence. Encompassing legal issues related to protection of traditional knowledge and biodiversity with intersecting provisions of CBD and TRIPS. Protection of Traditional cultural heritage will not be discussed. The study will analyse the protection of TK and Biodiversity through legal instruments available in territorial and Non-territorial jurisdictions. Patent mining has been used to extract patents related to Biodiversity by retrieving information from Patent databases by using International Patent Classification by defining keywords related to the field.

The study will contribute to substantive knowledge for protecting and governing TK and biodiversity. Too much attention has been paid to negate patents filed by companies; however attention has not been given to the potential role IPR can play in economic gain by communities. The study will contribute to substantial knowledge in the field that is TRIPS plus for protecting TK and Biodiversity for further access and benefit sharing and by mapping strategies of innovation for economic gain.
1.11 Chapters

Chapter 1, introduces the topic for study of Biodiversity and Traditional Knowledge. It informs about the course of action taken for the study with the purpose, objective of research, significance and scope with research method for the proposed study.

Chapter 2 on "History of the Intellectual Property Rights, Biodiversity, Traditional Knowledge and Innovation " informs about the original initiation for protection of Intellectual Property Rights and how the monopoly rights percolated into patent activities accruing through Biodiversity and Traditional knowledge.

Chapter 3 deals with "Governance and Protection of Biodiversity in Areas Within National Jurisdiction (AWNJ) and Areas Beyond National Jurisdiction (ABNJ): issues and challenges". The Chapter studies the legal governance for protection and conservation of biodiversity for territorial as well as marine genetic resources in areas within National Jurisdiction and beyond National Jurisdiction. Compatibility of CBD with UNCLOS is dealt with Tragedy of commons that once applied to plant genetic resources. Bioprospecting policy issues are also studies for marine genetic resources.

Chapter 4 studies "Bioprospecting, Biopiracy, Patenting and Disclosure of Origin of Biological Resources for Access and Benefit Sharing". Bioprospecting leads were fetched through patent mining from Genetic Resources. Disclosure of Origin of Genetic resources is discussed. Ex situ plant genetic resources collected before CBD enactment is also studied. Some biopiracy cases are analysed. Commercial products from marine genetic resources specially drugs and molecular biology tools like polymerases are also studied.

Chapter 5 discusses "The Complex Regime of International Legal Instruments the Regime of CBD, TRIPS, UPOV, ITPGRFA and Nagoya Protocol" along with the framework and timeline of treaties. The overlapping regime is also discussed with harmony and conflict between CBD, TRIPS and ITPGRFA. Protocol initiation and options for least or maximum protection common in all treaties is also discussed.

Chapter 6 deals with "Legal provisions for protection of Genetic Resources and Traditional Knowledge". Countries that have enacted legal provisions for Disclosure
of Origin of Biological Material are discussed like Belgium, Denmark, Germany, China, Sweden, Italy along with countries that strictly ask information about traditional knowledge in patent document. Some countries having enacted sui generis protection for Traditional knowledge are also discussed.

Chapter 7 provides some ideas that can be used for "Redesigning Strategy towards Innovative models for protection of Traditional Knowledge and Biodiversity", like a creative commons type licence for traditional knowledge. Proposal is also made to provide the traditional knowledge holders Co-Applicants in patent document, as already done by University of South Australia and Griffith University. Global bio collecting society type of trust is also proposed with sustainable tourism.

Chapter 8 The last Chapter provides an overall conclusion on how Traditional Knowledge and Biodiversity though having different nature of human intervention can be coherently used to conserve and sustainably manage BD and TK with strategic use of policy redesigning. The compatibility of TRIPs with strong protection for GI that has TK embedded can be used. Bioprospecting of Marine Genetic resources can be strategically used to conserve BD and to achieve Sustainable Development Goals along with Aichi Targets. Traditional Knowledge and Biodiversity can be strategically used to empower local communities by creating niche product.

1.12 Conclusion

The review of literature illustrates conflicting provisions of legal treaties in force. The provisions also seek into the strength of National laws for additional protection. The way forward would be not just looking up to the International Framework for instructions and Harmonisation, rather the impetus needs to be on strengthening National laws by having TRIPS –plus provisions or another strong sui-generis system that is enforced bilaterally through contract. The WIPO-IGC was established in 2001 and yet there is just a draft text with brackets to be seen. Simple documentation betrays ethical issues of traditional communities and they don’t understand the ontology of the structure of documentation. The way forward seems community involvement with scientific and legal support. The provisions for protection will come up because of demand from the community. It would depend on the market need of
aligning traditional knowledge that has centuries of experimental validation with market forces through structured strategy. Perpetual Copyright, trade secrets, Geographical indications have provisions that can be readjusted to incorporate traditional knowledge and Genetic Resources. The products from TK and GR needs to go through the innovation chain of scaling up. It is high time that developed and developed countries come together on a common platform for the betterment of traditional communities and protection of genetic resources. The study would contribute to knowledge by bringing discussions of existing legal framework and interventions needed for TK holders for protection of their creations., as also provided by Article 34 \(^\text{62}\) and Article 31 \(^\text{63}\) of United Nations Declaration on the Rights of Indigenous Peoples

“Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.”

\(^\text{62}\) Article 34 "Indigenous peoples have the right to promote, develop and maintain their institutional structures and their distinctive customs, spirituality, traditions, procedures, practices and, in the cases where they exist, juridical systems or customs, in accordance with international human rights standards.” stated in Annex to Resolution adopted by the General Assembly 61/295 during 107 \(^\text{th}\) plenary meeting on 13 September 2007 on United Nations Declaration on the Rights of Indigenous Peoples available at http://www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf