PROTECTION OF TRADITIONAL KNOWLEDEGE FROM BIOPIRACY: A STUDY WITH SPECIAL REFERENCE TO SIKKIM

A Dissertation submitted

To

Sikkim University

In Partial Fulfillment of the Requirement for the Degree of Master of Philosophy

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DECLARATION

I, Numa Limbu, hereby declare that this M.Phil. Dissertation entitled **"PROTECTION OF TRADITIONAL KNOWLEDGE FROM BIOPIRACY: A STUDY WITH SPECIAL REFERENCE TO SIKKIM"** was carried out by me in partial fulfilment of the requirements for the award of the Degree of Masters of Philosophy in Law is a record of original and independent research work done by me during July 2016-January 2018 under the supervision and guidance of Dr.Sonam Yangchen Bhutia, Assistant Professor, Department of Law, Sikkim University. The Dissertation has not been submitted partially or wholly for the award of any degree or diploma in any other university in India or abroad.

Place: Gangtok, Sikkim. **Numa Limbu**

Date: 7th feb, 2018. **M.Phil. Scholar Reg. No.16/MPLW/04**

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CERTIFICATE

This is to certify that the dissertation entitled "**PROTECTION OF TRADITIONAL KNOWLEDGE FROM BIOPIRACY: A STUDY WITH SPECIAL REFERENCE TO SIKKIM**" submitted to the Sikkim University in partial fulfilment of the requirement for the degree of Masters of Philosophy in Law is a record of bona fide research work carried out by **Miss Numa Limbu** during July 2016-January 2018 under my supervision. All the assistance and help received during the course of investigation have been duly acknowledged by me. I recommend that the dissertation be placed before the examiners for their consideration for the award of M.Phil. Degree.

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Protection of Traditional Knowledge from Biopiracy: A study with special reference to Sikkim

Submitted by **Miss Numa Limbu** under the supervision of **Dr. Sonam Yangchen Bhuita,** Assistant Professor, Department of Law, School of Social Sciences, Sikkim University, Gangtok- 737102, India.

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PREFACE

There has been a great change in the world in recent years. Knowledge is now regarded as important aspects for development and prosperity in a country. For various reasons traditional knowledge (TK) has become a grave issue. Indigenous and traditional peoples of the world constitute about 6% of the world population. Their intellectual properties, TK has been exploited and misappropriated by various researchers and MNCs. They being the real owner do not get to exploit their knowledge. They do not get the share or profit which arise out of the knowledge that they have created. The protection measures of TK is neglected and not taken into account. Due to lack of proper protection mechanism biopiracy takes place. Biopiracy is not new to any country having huge TK. There are many instances of biopiracy and how it has affected the indigenous people of a particular country. India has a bulk of TK and the issue of biopiracy is very old. There are many cases of biopiracy on TK of India the famous e.g. Neem, Turmeric and Basmati case.

To highlight the issue of biopiracy on TK, especially in India and Sikkim I, the researcher, have taken up this research work. This research makes a humble effort to show the root cause of biopiracy and the importance of TK and a thorough study of different international and national laws, regulations, declarations, treaties, conventions for protection of TK. The gene rich developing countries face a lot number of threat, one of such example is claiming patent over the old traditional methods, practices etc. The root cause of biopiracy on traditional knowledge is due to lack of proper protection or a specific legislation.

Sikkim is a state rich in biological resources and holds a vast amount of TK. The issue of biopiracy is prevalent in Sikkim. In this paper the various issues of biopiracy, the cases and the protection measures are discussed.

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ABBREVIATIONS

ABS	Access and Benefit Sharing
ASEAN	Association of South East Asian Nations
BMCs	Biodiversity Management Committees
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agriculture Research
CGRFA	Commission on Genetic Resources for Food and Agriculture
CPRs	Common Property Resources
ETC	Action Group on Erosion, Technology and Concentration
EU	European Union
FAO	Food and Agriculture Organization
FTA	Free Trade Agreement
GATT	General Agreement on Tariffs and Trade
GNWT	Government of the Northwest Territories
GRAIN	Genetic Resources Action International
HYVs	High Yielding Varieties
IARCs	International Agriculture Research Centre
IBRD	International Bank for Reconstruction and Development
IKS	Indigenous Knowledge System
ILO	International Labour Organization
IP	Intellectual Property
IPGRI	International Plant Genetic Resources Institute
IPRs	Intellectual Property Rights
ITK	Indigenous Technical System
ITO	International Trade Organization
MNC	Multinational Corporation
NBA	National Biodiversity Authority

OECD	Organization for Economic Co-operation and Development
PBRs	Plant Breeders' Rights
PCT	Patent Co-operation Treaty
PGRFA	Plant Genetic Resources for Food and Agriculture
PIC	Prior Informed Consent
PLT	Patent Law Treaty
PVP	Plant Variety Protection
PVPA	US Plant Variety Protection Act
TBGRI	Tropical Botanical Gardens Research Institute
TEK	Traditional Ecological Knowledge
TK	Traditional Knowledge
TKDL	Traditional Knowledge Digital Library
UDHR	Universal Declaration on Human Rights
UN	United Nations
UNCCO	UN Convention to Combat Desertification
UNCED Development	United Nations Conference on Environment and
UNCTAD	United Nations Conference on Trade and Development
UNDRIP Peoples	United Nations Declaration on the Rights of Indigenous
UNESCO Organization	United Nations Education, Cultural and Scientific
UPOV Plants	International Union for the Protection of New Varieties of
USPTO	US Patent and Trademark Office
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

CHAPTER 1

INTRODUCTION

1.1 STATEMENT OF PROBLEM

"Traditional Knowledge" (hereafter referred to as TK) also known as "Indigenous Knowledge", "local knowledge", "folk knowledge" etc, means the understanding that has been followed since generations and which has contributed to the general knowledge on sound environment principles and management, such as in forest protection, soil protection, seed conservation and crop biodiversity. TK includes original knowledge, tradition, and customary medical knowledge and often used to develop profitable products such as new pharmaceuticals, herbal medicines, seeds, cosmetics, personal care and crop protection products. World Intellectual Property Organization (hereafter referred to as WIPO), defines Traditional knowledge as the experience, techniques and performance that are developed, and carried on through generations in a society, and often forming part of its intellectual or religious characteristics. The protection of traditional knowledge is of vital importance to socio-economic and technological development of every country containing traditional knowledge. Since, the indigenous people and the local communities hold the knowledge that are very important and has tremendous commercial value most of the corporations are trying to get benefits from it. With the advent of Intellectual Property Rights especially granting of patents under the Trade Related Aspects of Intellectual Property Rights (hereafter referred to as TRIPs), misuse of the traditional knowledge takes place, as the communities' rights are ignored and more over the knowledge that was generally shared freely are being curtailed as

private rights are given more importance. One of the important issues regarding misappropriation of TK is the "Biopiracy" phenomenon.

Biopiracy is referred to the use of intellectual property systems to validate the illegal ownership and monopoly over biological resources and the product and processes made out of the resources that have been used over centuries in underdeveloped countries. Patent claims over the biological, resources and understanding of traditions which are the novel, and based upon the knowledge and understanding of the indigenous people also constitute 'biopiracy'. The idea of piracy was utilized as a basis for including intellectual property rights in a worldwide trade agreement, there was an assertion that United States was losing millions of dollars a year because of global piracy of copyrighted and patented works. One main reply to these piracy claims was the formation of the World Trade Organization (hereafter referred to as WTO), along with the landmark implementation "Agreement on Trade-Related Agreement on Intellectual Property Rights", that recognized minimum levels of intellectual property standards for all member states. The corporations of the developed countries like U.S, E.U by appropriating the biodiversity and traditional knowledge of the developing countries like India and China perform the act of piracy. The concept of biopiracy on TK is complicated and controversial it involves directly with the concept of intellectual property rights (hereafter referred to as IPRs) in biological resources, and many international treaties.

There is a great need for protection of Traditional Knowledge. The main problem is there is no specific provision for the protection of the Traditional Knowledge under the TRIPs Agreement so when the Multinational Corporations engage in act of biopiracy by taking

the genetic resources and associated traditional knowledge from biodiverse developing countries without permission, then patenting related inventions but failing to share any of the resulting commercial profits, the issues remains unsolved.

Traditional Knowledge as we can understand is also an intellectual property because the indigenous people use their understanding about the plants and the genetic resources. So, seeking Intellectual property rights over something that has been already in practice must not be allowed but the patent is granted over such products or processes. There are certain provisions relating to protection of TK under the Convention of Biological Diversity (hereafter referred to as CBD), but when the decisions are to be made between the provisions of CBD and TRIPs the TRIP's provisions are given primacy. The Intellectual Property Rights system are biased towards western knowledge systems which reduce biodiversity to its chemical or genetic structure, the indigenous systems get no protection but piracy of the indigenous knowledge is protected.

There is no concept of prior informed consent which means the indigenous people aren't informed by the researchers about what they are doing. The researchers do not avail the consent from the traditional knowledge holders. They just do their research work and use the TK relating to certain resource to invent and claim patents for the same. They focus on private right and claim all the benefits arising out of the inventions to themselves. Soon, after patents are granted, there is a possibility of the price of product to rise tremendously which cause problem for the people who depend on them for various activities. The other problem that generates is the seeds, or product from a plant that were freely available to the farmers or the indigenous people would be very difficult to be

accessed because of the rise of the price. There is no proper mechanism that could help the traditional knowledge holders to stop biopiracy to takes place which infringes their rights of access and benefit sharing.

It is necessary to recognize the importance of Traditional Knowledge. The wild plants found in the forests were recognized by the indigenous people, out of which men and women over generations have bred the thousands of land races which are the basis of the world's agriculture. It is the TK that provides know how for developing crop varieties suited to the diverse climatic regions. The large scale granting of patents for genes and other biological materials and organisms leads to an even greater concentration of control over the world's food crops, such as maize, potato, soybean and wheat, in few global corporations. This has caused major damage to the rights of the communities who hold bulk of traditional knowledge as they are easy targets and much of the knowledge can be abstracted easily from them.

Traditional knowledge holders have used their understanding to bred the seeds and use particular method to cultivate the crops. With biopiracy on plant genetic resources people following traditional method are facing a lot of problems they have to buy new genetically modified seeds and pay royalties for each harvest. The new varieties like 'terminator' and 'traitor' seeds are genetically engineered to prevent the seed from reproducing itself naturally, this cause enormous risk not only for communities but biodiversity itself. Genetic erosion is one of the most important invisible impacts that are in long run manifested visibly with the loss of biodiversity. The right to livelihood is the basic human right but this is also threatened by patents on life in food and agriculture. Many inventions rely upon the knowledge and insight of local people. There are many

instance of biopiracy on genes or natural compounds from plants which are traditionally grown in developing countries. They are rice (31 patents), cocoa (7 patents), millet (1 patent), sweet potato (2 patents), rubber (8 patents).

India is regarded as one of the 17 mega-biodiversity countries with 2.4 per cent of the global land area and has 7 to 8 % of the listed species of the planet, making it more prone to biopiracy. Indian system of medicine Ayurveda, Unani and Siddha and folk traditions have used various plants for the treatment of common diseases. There are numerous indigenous communities in different states of India who follow their unique TK to deal with various activities e.g., treating a disease, or breeding varieties of seeds and applying special methods to cultivate crops. There are number of instances of biopiracy in India some examples are neem, turmeric and basmati case. India is TRIPs compliant. India has enacted Patent Act, 1970 which was amended on 2005, the Geographical Indication Act, 1999 and various other Act that recognizes the Intellectual Property Rights. The Wild Life Protection Act 1972, the Biological Diversity Act, 2002 and the sui generis Act i.e. Protection of Plant Varieties (PPV) and Farmers' Rights Act (2001) lay certain provisions recognizing the value of flora and fauna and the rights of the local and indigenous communities. Under Section 36(iv) of Biological Diversity Act the provision for protection of knowledge of indigenous people based on biodiversity is meant to be done either by creating a *sui generis* system or by registering such knowledge. For the protection of TK India has taken various initiatives under intellectual property rights, the Traditional Knowledge Digital Library (hereafter referred to as TKDL) is one of them; it protects traditional knowledge and to prevents granting of wrong patents. TKDL is an

Indian effort to help prevent misappropriation of TK belonging to India at International Patent Offices. By recording the TK, legally, it becomes public domain knowledge. Under the patent law, this means that it is considered to be prior art and hence is not patentable. Such a written record, is easily accessible to patent offices around the world, and would provide all such offices with a record of India's prior art. Although TKDL is formed it only has data about traditional medicines other type of TK are left out of it. Another problem with it is that it is only a preventive measure there is no strong legislation for protection of TK, against biopiracy. Apart from biopiracy on medicinal plants there are many instances of biopiracy on crops. Basmati rice is a specialty of India but a US company has availed patent on germplasm of it, though it was unique quality of rice and was found only in India but the patent granted to US Company could not be cancelled.

Sikkim is regarded as one of the biodiversity 'hotspot' in India. Sikkim has approximately over 4500 flowering plants, 550 Orchids, 36 Rhododendrons, 16 Conifers, 28 bamboos, 362 Ferns and its allies, 9 Tree Ferns, 30 Primulas, 11 Oaks, over 242 Medicinal plants, 144 plus mammals, 550 birds, 48 Fishes and over 600 butterflies. Sikkim has its own set of TK, which they have either inherited or innovated and use it in day to day basic. TK is a heritage of communities and any exploitation of such knowledge should be done with benefit of the community. People fail to realise the value of TK. As Sikkim has diverse biological resources many private corporations and researchers have tried to take undue advantage of it. Sikkim is regulated by the Indian Biological Diversity Act, 2002 and has also established the Sikkim Biodiversity Board; a statutory body under Sikkim Biological Diversity Rules, 2006. The board has many

functions the important one is to take steps to build up database and to create information and documentation system for biological resources and associated traditional knowledge through biodiversity registers and electronics data bases, to ensure effective management, promotion and sustainable uses. Most of the TK is orally transmitted and so it is very hard to avail protection for something that is not recorded. There is a strong need to enact legislation either at national level or state level for protection of TK.

The indigenous people are not well aware of the problems associated with granting of IPRs. There were many instances of biopiracy in Sikkim, in 2016, the Sikkim Government issued an advisory notice to all the tourism stakeholders alerting on the visit of two foreign nationals allegedly involved in bio-piracy of protected flora from Sikkim. Another instance of biopiracy was in 2007 when three French Nationals were held allegedly in possession of 41 insects (including butterflies and moths) , in contravening the Wildlife Act of 1972. There are various cases, where the rights of traditional knowledge holders are affected and it is difficult to be satisfied with the remedies which are costly and uncertain.

1.2 LITERATURE REVIEW

- Ajeet Mathur, "*Who Owns Traditional Knowledge?"* Vol.38, Economic and Political Weekly, (2003) this article provides an overview of the issue relating to the ownership of Traditional Knowledge. The ongoing international debate on the question of whether rights to use Traditional Knowledge belong inside IPR regimes or outside it. The growing issues of protecting Traditional Knowledge are discussed. The author also highlights the need for adopting a legislative framework to deal with the issues of biopiracy and protection of traditional knowledge.
- Daniel F. Robinson, "*Indigenous Peoples' Innovation; Intellectual Property Pathways to Development*", ANU Press. (2012) in this book the author describes about the idea of biopiracy and how can it be tackled. He highlights the deficiency that is present under the current international treaty to deal with the problem of biopiracy. He talks about how worldwide agreement on the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization 2010 to the Convention on Biological Diversity (CBD) has fallen short to resolve the problem. He suggests that there must be an effective instrument to look into the problem or the TRIPs must be amended and provision for protection of traditional knowledge must be guaranteed.
- Devinder Sharma, "*Digital Library on Indian Medicine Systems: Another Tool for Biopiracy*", Vol. 37, Economic and Political Weekly, (2002), in this article the writer highlights the role that the digital library has played for providing safeguard on Indian Medicine against biopiracy. He recommends the initiative

undertaken by the Indian Government, but he highlights the issue of the absence of global safeguards, which would turn the digital library a wanted source of information on bio-prospecting for private companies. The writer points out correctly that mere having of digital library cannot stop bio piracy a global safeguard must be there.

- Ho, Cynthia M., "*Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*", 39 U. Mich. J. L.Reform (2006) in this article the author provides afresh and multi-dimensioned approach to a long-standing claim of biopiracy patents made by developing countries and communities. The author explains the underlying conflicts, misconceptions, and historical biases that have predisposed some to biopiracy claims. Similarly, the Article presents a new perspective on how the present landscape of international agreements, as well as negotiation stances, has failed to lead to satisfactory resolution of biopiracy claims despite years of heated discussion within major international forums, including the World Trade Organization, the United Nations, and the Convention on Biological Diversity.
- Ikechi Mgbeoji, "*Patent and Traditional Knowledge of the Uses of Plants: Is a Communal Patent Regime part of the Solution to the Scourge of Biopiracy*?" Vol.9, Indina University Press (2001), the author discusses how the Patent Law System is problematic and controversial. One of the major concerns that have been highlighted in this article is regarding the genetic diversity of plants and the role of patents in protecting traditional knowledge relating to plant use. The author writes about the changes that can be adopted by Patent laws so as to

include the provisions of equitable sharing of benefits. Lastly he suggests that that the standards of patentability in matter relating to life forms and Traditional Knowledge of the use of plants must be raised.

- Javier Garcia, "*Fighting Biopiracy: The Legislative Protection of Traditional Knowledge*" Volume 18 (2007), in this article the author discusses about how a county can fight against the issue of biopiracy. According to the author adopting domestic legislation would provide the best means to regulate and control foreign entities seeking to extract and exploit traditional knowledge from vulnerable indigenous communities.
- John Merson, "*Bio-Prospecting or Bio-Piracy: Intellectual Property Rights and Biodiversity in a Colonial and Postcolonial Contex*t", Vol. 15, The University of Chicago Press on behalf of The History of Science Society, (2000) , in this article the author discusses about how the various countries which were colonized moved out of the situation. The article in short gives the image of the situation which took place from documentation of new medicines to seeking patent for the same. The author also highlights the plight of countries whose biological resources that they had been using were applied for creating new products and availed patent for the same. The author also puts light on the need for adopting Convention on Biological Resources as more biological resources were imported from the colonies and to provide a strong belief to safeguard the biological diversity. The importance of indigenous people is also highlighted as they are the ones who have more knowledge about the resources and its usefulness. Number of examples is cited about how the indigenous people with traditional knowledge

helped in safeguarding the biodiversity. The main area that the author fails to discuss is how to protect the indigenous people and their bulk of knowledge.

- John Reid, "*Biopiracy: The Struggle for Traditional Rights, vol.34, University of Oklahoma College of Law* (2009-2010), the writer identifies the problem with the traditional knowledge i.e. it's neither protected nor organized. Moreover the traditional knowledge is passed down for generations and not recorded. The author highlights the importance of traditional medicines and how biopiracy is causing threat to the medicines based on such resources.
- Kuei-Jung Ni, "*Traditional Knowledge and Global Lawmaking*", Vol.10 NW.J.INT'L HUM.RTS.(2011), in this article the author tries to explore how these key global system engage in the protection of Traditional Knowledge by formulating rules .The present global legal frameworks that deals with Traditional knowledge is examined.
- Martin Khor, "*Intellectual Property, Biodiversity and Sustainable Development*," Zed Books Ltd, (2002), this book though titled intellectual property and biodiversity, highlights more about Traditional Knowledge and the community's rights. The author talks about how Intellectual property rights have become a threat to traditional knowledge. The author also highlights the issue of misappropriation of traditional knowledge under the biopiracy phenomenon. The book provides views of indigenous people for dealing with the issue of biopiracy.
- Pranay Bantawa & Ritu Rai, "*Studies on ethnomedical plants used by traditional practitioners, Jhankri, Bijuwa and Phedangma in Darjeeling Himalaya*", Vol. 8(5) (2009), in this research work the researchers have mentioned a huge range of

plants that are used by the traditional practitioners. This paper highlights the wide varieties of traditional knowledge on medicinal plants and their usages. The researchers' suggests that all this plants with the medicinal values must be protected and one of the ways to do that is by making a data base.

- Rajshree Chandra, "*Intellectual Property Rights: Excluding Others Rights of Other People*", Vol.44, Economic and Political Weekly, (2009), the writer correctly put forward the issue relating to rights granted under Intellectual Property Rights. According to the writer Intellectual Property Rights not only grants the holder property rights over the products of his intellectual labour, but also simultaneously takes this rights away from others, by prohibiting others free use of their self owned mental labour to create the same product. According to him using particular idea, knowledge does not deplete or exhausts an idea. The other rights of traditional knowledge holder and farmer's rights are discussed by the author.
- R. D. Singh & S.K. Mody, H. B. Patel, Sarita Devi, C.M. Modi and D.R. Kamani , "*Pharmaceutical Biopiracy and Protection of Traditional Knowledge*", Vol.2 (2014), in this article the writers' have clearly explained what are the major issues relating to bio piracy or bio prospecting by pharmaceutical industry. How the traditional knowledge based bio-prospecting are used to significantly cut costs of pharmaceutical Research and Development. Due to this the Pharma-industry looks at medicines and products that have been developed by local communities in older cultures like India, Africa and China. This according to the writers causes misuse of the traditional knowledge held by particular people. As no particular

laws are there to look into the matter of biopiracy it is difficult to protect the old traditional knowledge. According to the writers the patent law also helps in bio prospecting. The writers highlight the treaties that deal with biopiracy.

- Rebecca M. Bratspies, "*The New Discovery Doctrine: Some thoughts on Property Rights and Traditional Knowledge*", University of Oklahoma College of Law (2006/2007), in this essay the writer discusses how the value of biodiversity associated traditional knowledge has gained importance. The essay provides a new idea of group ownership to the biological materials rather than fighting for the issue of private and state ownership.
- S.Biber-Klemm & T.Cottier, "*Rights to plant genetic Resources and Traditional Knowledge: Basic issues and perspectives*",(2006), the book highlights the current legal status of plant genetic resources and traditional knowledge. The author suggests that there must be necessary changes that need to be brought in the present Intellectual Property Rights system so that the rights of the Traditional knowledge holders are safeguarded. The book discusses the problems and gives suggestion of how plant genetic resources ad traditional knowledge can be protected.
- Vandana Shiva, "*Protect or Plunder?, Understanding Intellectual Property Rights*", Zed Books, Ltd. (2001), this is one of the best book written regarding IPRs specifically patents and the various disadvantages that it carries with it. The bad side of patenting on living organisms is mentioned in this book. Though the technology rich countries encourage the same it is not possible for the developing countries to encourage for IPRs. There are many ill effects of the same, many

authors praise the discovery or creation of new inventions and the various rights that the inventor is awarded but this is not a win situation because together with developments there are major disadvantages of IPRs in human society. In one of the chapter she has discussed the threats that are caused to biodiversity. With the introduction of patents on biological resources there has been a grave need for a control mechanism which could raise the question of ethical considerations. She also argues that patents related to biological resources have major implications for the conservation of biodiversity and its sustainable use. She also highlights the issue of biopiracy in one of her chapter, a whole concept of biopiracy or bioprospecting is given. The author also points out certain cases of biopiracy.

1.3 RESEARCH OBJECTIVES

- To critically analyze the laws for protection of Traditional knowledge in International and National level.
- To find various lacunas in international regimes and to identify gaps and opportunities for protection of Traditional knowledge.
- To study various cases and disputes of biopiracy on traditional knowledge in India.
- To study the instances of biopiracy and protection measure of Traditional Knowledge in India and Sikkim.

1.4 RESEARCH QUESTIONS

- What are the various laws for protection of traditional knowledge at the International and National level?

- Why there is a need to formulate legislation for protection of traditional knowledge?
- What are the various issues relating to biopiracy on traditional knowledge in India?
- What protection is granted to the traditional knowledge holders in Sikkim and what are

  the steps that are taken by Sikkim Government to deal with biopiracy issue?

1.5 HYPOTHESIS

- The existing legal framework is not adequate enough to deal with the problem related to Traditional knowledge.
- Biopiracy is taking place due to inadequacy of protection by the law in India and Sikkim.

1.6 RESEARCH METHODOLOGY

The methodology adopted by the researcher is empirical and doctrinal in nature. In order to achieve the objective i.e. to find the instances of biopiracy in Sikkim, the researcher has collected primary data related biopiracy on traditional knowledge from various Departments and Members of Biodiversity Board and traditional knowledge holders through interview and questionnaire methods. Various statutes like the Patent Act, 1970, the Biological Diversity Act, 2002, Sikkim State Biological Diversity Rules, 2006, the Wildlife Protection Act, 1972, the Geographical Indications Act, 1999 and the Protection of Plant Varieties and Farmers' Rights Act, 2001, the Schedule Tribes and Other

Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006 has been analyzed. Secondary data like books, articles, research papers, and journal relating to the issue has been taken into consideration. The research also includes study of case laws. Use of the internet is also be made to gather important information relating to the subject of study.

The research work is divided into following chapters:-

Chapter I: INTRODUCTION is an introductory chapter, which gives a gist of the problems relating to biopiracy on traditional knowledge. The statement of problem followed by research objectives, questions, hypothesis and literature review are mentioned in this chapter.

Chapter II: CONCEPT OF TRADITIONAL KNOWLEDGE AND BIOPIRACY defines the meaning of "traditional knowledge" and "biopiracy". This chapter also highlights the evolution of biopiracy and traditional knowledge.

Chapter III: LEGAL FRAMEWORK FOR PROTECTION OF TRADITIONAL KNOWLEDGE: INTERNATIONAL AND NATIONAL LEVEL critically examines the protection measures that are awarded to traditional knowledge at international and national level. All the Acts, Declaration, Conventions, treaties are discussed in this chapter.

Chapter IV: THE CASES AND DISPUTES OF BIOPIRACY IN INDIA discusses cases of biopiracy in India. This chapter highlights how the multinational companies and various researchers have tried to claim patent rights over the resources having traditional knowledge of India. This chapter also makes a clear point that without a proper documentation of the traditional knowledge people can easily claim patent rights over it.

Chapter V: PROTECTION OF TRADITIONAL KNOWLEDGE FROM BIOPIRACY IN SIKKIM, in this chapter the importance of traditional knowledge in Sikkim is discussed. It also highlights the dependency of the people of Sikkim on the traditional practices. This chapter explains how biopiracy is taking place and the methods that are adopted by the Government and the concerned authorities to deal with it.

Chapter VI: CONCLUSION AND SUGGESTIONS this chapter summarizes the research by suggesting necessary steps to deal with the issue of biopiracy on traditional knowledge in Sikkim.

CHAPTER 2

CONCEPT OF TRADITIONAL KNOWLEDGE AND BIOPIRACY

2.1 INTRODUCTION

Since the evolution of mankind, knowledge has been treated as the most cherished possession of humanity. Knowledge was purely a subject matter of fame and reputation which had been spread with no returns in the ancient times. However, various developments that took place in the evolution of societies recognized knowledge as a property and many rights were attached to the knowledge holder. There is no universal definition of traditional knowledge however, scholars typically define it either as knowledge developed by indigenous communities or tradition based intellectual activity.[1] Knowledge is evolved through lots of trials and has been passed from generation to generation constantly evolving to meet the changing needs of the people of a specific territory.[2] It is held collectively by a community and not limited by any specific field of technology. Traditional knowledge therefore encompasses everything from plant cultivation to medicinal remedies to food recipes.[3] "Knowledge about characteristics of plants having healing properties and technology of its use gives medicinal plants their social and economic value. This use of technology has been acquired through thousands of years of experience, trial and error and generation to generation refinement. As a result

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[1]Javier Garcia, *Fighting Biopiracy: The Legislative Protection of Traditional Knowledge*, (Berkeley La Raza Law Journal, Vol.18, 2007).

[2]Erin Donovan, *Beans, Beans, the Patented Fruit: The Growing International Conflict over the Ownership of Life,* 25 (LoY. L.A. INT'L & COMP. L. REV. 117, 126-27 2002).

[3]Stephen Hansen & Justin Vanfleet, *Traditional Knowledge and Intellectual Property: A Handbook on Issues and options for Traditional Knowledge Holders in Protecting their Intellectual Property and Maintaining Biological Diversity*, 3 (2003); Gina Marie Mcandrews, *Utilization Of Medicinal Plant Species In The Zapotec Community Of Yatzachi El Bajo, Oaxaca, Mexico* (1995), Shr.Aaas.Org/Tek/Handbook/Handbook.Pdf.

of this, age old communities have developed their knowledge of the plant, animal and mineral resources to a grown up and scientifically sound technology, which reflects in old traditions of healing science like Ayurveda and Siddha. In addition to this, ethnic communities i.e. tribal, island and local have developed their own knowledge base about the flora, fauna and mineral wealth of their region"[4].

2.2 Definition of Traditional Knowledge

"The term traditional knowledge has been defined by many but till now an exact definition has not been made. It is tagged in various manners, traditional knowledge (TK), indigenous knowledge (IK), and local knowledge that are usually referred the old traditions and practices of certain indigenous, local and religious communities" [5]. According to the United Nations Educational, Scientific and Cultural Organization (hereafter referred to as UNESCO, "Traditional Knowledge is the cumulative and dynamic body of knowledge, knowhow and representations possessed by peoples with long histories of interaction with their natural milieu. It is intimately tied to language, social relations, spirituality and worldview, and is generally held collectively".[6] As defined by the World Intellectual Property Organization (hereafter referred as to WIPO) TK includes the fictitious, inventive or scientific works, performances, scientific discoveries, designs, characters, names and signs, secret information that are based on tradition and all creations with logical action in the development, technical, fictional or

[4]Pharmaceutical Biopiracy and Protection of Traditional Knowledge, *available at https://www.omicsonline.org/open-access/pharmaceuticals-biopiracy-and protection-of-traditional-knowledge-.pdf* (last visited on January 17,2018)
[5]Traditional Knowledge*, available at http://shodhganga.inflibnet.ac.in/bitstream/10603/22605/9/09_chapter2.pdf* (last visited on May 12, 2017).
[6]Supra note 4.

creative areas.[7] Under Article 8(j) of the CBD, TK is defined as knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles important for the protection and sparing use of biodiversity[8]. "The GNWT (Government of the Northwest Territories) policy defines TK as 'information and morality that has been developed through knowledge, study, from the land or from spiritual teachings, and passed on from one generation to another."[9] There are many definitions of "TK but the main characteristics are cultural values and customs that are being passed on from generations and to maintain a balance with the ecosystems."[10]

Anthropologist Johnson[11] defines traditional knowledge as organization of facts built by a group of inhabitants existing in close contact with nature. The characteristics of traditional knowledge include:

- Creation over a long period of time which means it should be passed down from generation to generation;
- As new knowledge are integrated there must be a constant improvement;
- Both creation and improvements should be with the effort of group.

[7] Intellectual Property Needs and Expectations of Traditional Knowledge Holders, WIPO Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge 25, (1998-1999) (WIPO Publication 768E).
[8] Supra note 5.
[9] Definitions of Traditional Knowledge, *available at https://www.nafaforestry.org/forestry.org/forest_home/documents/TKdefs-FH-19dec06.pdf* (last visited December 23, 2017).
[10] *Ibid.*

[11] Quinn ML, *Protection for Indigenous Knowledge: An International Law Analysis*, 287-313, ST. Thomas /law Review 14: (2001).

2.3 Definition of Biopiracy

Vandana Shiva defines the term biopiracy as the applicability of intellectual property right systems which validates the restricted possession and control over biological matters and biological outputs and process that have been in constant use throughout the centuries in non-industrialized countries. Claiming patent over traditional knowledge and biological resources based on the understanding, originality and intelligence of the indigenous people belonging to underdeveloped countries are 'biopiracy.'[12] Issac and Kerr describe biopiracy as a theft of valuable resources for the commercial gain by developed counties and multinational corporations.[13] It represents a disingenuous repackaging of TK in order to secure monopoly rents for the biopirate while excluding the original inventor from a claim to these rents. Not only the exploitation but any unauthorized use by corporations and individuals of biological resources for commercial gain without the permission of and without adequate reward going to the communities that have nurtured the resources and developed the knowledge over generation's amounts to biopiracy. It raises significant inequity concerns since much of the world's traditional knowledge and associated biodiversity are held by the world's poorest.[14] According to American Heritage Dictionary biopiracy is "the commercial development of biological compounds or genetic sequences by a technologically advanced country or organization without obtaining consent from or providing fair compensation to the peoples or nations

[12]Vandana Shiva, Protect or Plunder: Understanding Intellectual Property Rights, , 49, (Zed Books Ltd., London,
2001).

[13] Grant E. Issac and William A. Kerr, *Bioprospecting or Biopiracy, The Journal of World Intellectual Property,* (37, Vol. 7, No. 1, January 2004).

[14]William A. Kerr and R. Yampoin, Adoption of Biotechnology in Thailand and the Threat of Intellectual Property Privacy, *Canadian Journal of Agricultural Economics*, 48 (4), 597- 566(2000) in Grant E. Issac and William A. Kerr, "Bioprospecting or Biopiracy," *The Journal of World Intellectual Property*, 37, (Vol.
7, No.1, January 2004).

in whose territory the materials were discovered".[15] The Wikitionary, Creative Commons Attribution defines biopiracy as "the appropriation of indigenous biomedical knowledge, especially by patenting naturally occurring substances".[16] The misappropriation and commercialization of traditional knowledge and genetic resource of the local communities is defined as biopiracy. The natural resources such as plants, trees, seeds etc. that are freely available are commercialized by using the methods followed by the local people from generations. "Biopiracy is mostly resorted by the pharmaceutical, the agro food and cosmetic firms. They aim the biodiversity rich places so that they can produce an innovative product which guarantees their monopoly on them through patent system."[17] It is by learning the techniques from the indigenous people who hold the traditional knowledge the multinational corporations identify biological matter having medicinal significance and to abstract benefit from such matter they "they claim patent on products by conducting experiments in their labs"[18]. This violates the rights of the indigenous people who have been taming and continuously improving the locally available species since old times. "Natural resources are not subject to be patented such as plants, minerals, etc, but the rich corporations have started using the patents as a mode through which they can claim dominance over the natural world"[19]. "Enormous magnitude has been assumed with the massive growth in the biotechnology industry and

[15] American Heritage Dictionary of English Language, 5th ed. Houghton Mifflin Hartcourt Publishing Company, (2016) *available at www.thefreedictionary.com (* last visited on 11th May, 2017).
[16] Biopiracy-Definition and Meaning, *available at https://www.wordnik.com* (last visited on May 11, 2017)
[17] Biopiracy: The Vanishing point of Traditional Knowledge, *available at http://lawmantra.co.in/biopiracy-the-vanishing-point-of-traditional-knowledge-by-sidhant-tigga-and-sachin-mishra/* (last visited on May 12, 2017)
[18] *Ibid*
[19] *Ibid*

the possibility approved by the biological resources combined with the traditional knowledge."[20]

2.4 Evolution of Traditional knowledge

"Knowledge is important because the recognition and encouragement of practical, financial and communal transformation in societies would not be possible without having certain knowledge"[21]. Only if we possess such knowledge we can put that to work. The Oxford English Dictionary defines Knowledge as "expertise and skills acquired by a person through knowledge or learning, the hypothetical or sensible understanding of a subject, what is known in a particular field or in total , facts and information or consciousness or acquaintance gained by experience of a fact or situation"[22]. The great Greek Philosopher Plato defines knowledge as "justified true belief". "The unwritten knowledge or wisdom used continuously and developed through generations, coming out of experience through tradition, heritage, culture or family or social setup is called traditional knowledge. Indigenous knowledge is the sum total of the knowledge and skills which people specific to geographical area and culture possess, and which enable them to attain the best out of their natural environment"[23]. Most of this knowledge and skills have been passed down from earlier generations, each new generation adapt and add to this body of knowledge in an adjustment to changing circumstances and environmental

[20]Aditya Mishra, "*Biopiracy: The Vanishing point of Traditional Knowledge",* Vol.2, (2015). *Available at http://lawmantra.co.in/biopiracy-the-vanishing-point-of-traditional-knowledge-by-sidhant-tigga-and-sachin-mishra/* (last visited on May 12, 2017).

[21] 02_abstract.pdf *available at http://shodhganga.inflibnet.ac.in/ 02_absstract.pdf* (last visited on January 12, 2017)

[22]Knowledge- definition of knowledge in English*, available at https://en.oxforddictionaries.com (*last visited on May 12, 2017).

[23] Supra note 20

conditions and pass on the body of knowledge to the next generation, in order to provide them with survival strategies. An old African proverb states "when a knowledgeable old person dies, a whole library disappears."[24] Traditional knowledge helps in making decision regarding health care system, agricultural facilities, food security, management of natural resources and education. "There has been proliferation of terms such as traditional knowledge (TK), indigenous technical knowledge (ITK), and indigenous knowledge system (IKS)."[25]The following paragraph highlights the evolution of the concept of traditional knowledge and biopiracy.

The international history of traditional knowledge begins after World War II and runs in parallel with the recognition of indigenous peoples as "peoples".[26] The United Nations Charter, 1945 played a crucial role by emphasizing the need to recognize human rights and sovereignty of everyman and people.[27] Soon after this decolonization process began example India became independent in 1947, French Sub-Saharan African Colonies in 1960), but the indigenous peoples' did not benefited directly from decolonization as their rights to sovereignty could not override the principle of territorial integrity of the countries in which they were located.[28] In 1952 the International Labour Organization (hereafter referred to as ILO), together with other United Nations agencies, initiated the

[24] Supra note 20
[25] Indigenous Knowledge Web Resources in India with Special reference to Ayurvedic Resources, *available at http://www.ijodls.in/uploads/3/6/0/3/3603729/1-11232.pdf* (last visited on December12, 2017).
[26]Christoph Antons, "*The International Debate about Traditional Knowledge and Approaches in the Asia-Pacific Region*" in Chistoph Antons (ed), "*Traditional Knowledge, Traditional Cultural Expressions and Intellectual Property Law in the Asia-Pacific Region"*, 40-51, (2009).
[27] Charter of United Nation (adopted 24th October 1945) Preamble, Chapter 1.
[28] Peter Tobais Stoll & Auja von Hahn, "*Indigenous Peoples, Indigenous Knowledge and Indigenous Resources in International Law*" in Silke von Lewinski (ed), "*Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge and Folklore*"9, (2nd ed, 2008).

Andean Indian Program for the development of South American native Indians.[29] In the year 1957 same agency adopted the Convention with regard to the safety and "Integration of Indigenous and Other Tribal and Semi-Tribal populations especially in Independent Countries"[30] that recognizes the rights of the ownership for the population over their traditional territories.[31] But this did not promote the integration of the indigenous people inside the social order and did not preserve strictly the uniqueness of the societies. This was the reason that this Convention was rejected and was replaced in 1989 by the Convention that concerned with Indigenous and Tribal peoples in Independent Countries. The main objectives of this convention were to recognize the desire of the people which would help them to manage their own institutions, the possibility of life and development which could lead to preservation and recognition of their identities, languages and religions". Though the treaty did not mention explicitly of traditional knowledge and traditional cultural expressions, there are provisions that are relevant for understanding it. Under Article 23 (i) handicrafts industries based on rural community ideas, and traditional actions of the peoples concerned, such as hunting, fishing, trapping and gathering, was recognized as important factors in the protection and improvement of their cultures and in economic self-reliance and development". In addition, to this the Convention stresses the importance of the indigenous rights over their land. In particular, under Article 13(i) the governments are to respect the significance of the spiritual and cultures value of the peoples who are particularly concerned with the relationship

[29] Supra note 20

[30] It is an agency that recognizes the rights of the ownership for the population over their traditional knowledge especially in Independent Countries.

[31] Convention concerning the protection and Integration of Indigenous and other Tribal and Semi-Tribal populations in Independent Countries (adopted 26 June 1957, into force 2 June 1959) 328 UNTS 247 (ILO Convention 107/1957).

between the lands or territories while under Article 15(i) there must be some safeguards for the rights of people especially connected to the natural resources and their lands. People must have the rights to participate in the use conservation and sustainable management of the resources that are available to them.

The important initiative, born at local level also led to an official recognition of indigenous rights at United Nations level. In 1982, the growing issues for protection of indigenous communities structurally became part of the activity of the United Nations with the creation of the UN Working Group on Indigenous Populations within the frame of the UN Economic and Social Council. For the protection of the indigenous people a UN body was established under the name "Permanent United Nations Forum on Indigenous Issues". The recognition of the rights of indigenous peoples in the 70's and 80's did not lead to the creation of autonomous concept of traditional knowledge. However, it was essential in order to acknowledge the existence of an extensive corpus of knowledge, in the broad sense of the term, belonging to indigenous communities and other subject to misappropriation. In this regard, the first and most famous case was represented by the song "El Condor Pasu", belonging to the Andean folk tradition, which turned into a bestselling hit by Simon and Garfunkel in 1970. This provoked the protestations of the Bolivian Government, while the indigenous communities remained silent.[32]

The Convention on Biological Diversity was signed in Rio de Janerio on 5th June 1992, an international treaty with the objective of developing strategies for the conservation of

[32] Michael Halewood, "*Indigenous and Local Knowledge in International Law: A Preface to Sui Generis Intellectual Property Protection*", 953, 967-968, (44 Mchill L, , 1999).

biodiversity and of the sustainable use and fair sharing of biological resources.[33] According to this Convention the pre-existing idea about the genetic resources were the "heritage of mankind" and therefore freely accessible. Under Article 8(j) of the Convention each contracting party shall in consistency to its national legislation respect, preserve and maintain knowledge, based upon indigenous innovations and practices. Together with this the convention also laid down that there should be sustainable use of those resources and the rights of the indigenous people must be protected. When the knowledge is used for any research or inventions than the people must get the benefits that would arise out of it.[34]

For the first time, the rights of local communities as depositaries of a body of knowledge were recognized. The above mentioned Article highlights the important role played by the local communities for protection and conservation of biodiversity and environment.[35] Traditional Knowledge is further mentioned in Article 10(c) according "to which contracting parties shall always encourages traditional use of biological resources that are in tune with traditional cultural practices and would lead to conservation or sustainable use requirements so that the biological resources that are used by the indigenous people be protected"[36]. CBD has been historically important as it has inspired treaties, dealing with different subjects, to undertake the concept of traditional knowledge into account. "The FAO conference passed the International Treaty on Plant and Genetic Resources for

[33] UN Convention on Biological Diversity 176 UNTS 79 (CBD) *available at www.cbd.int* (last visited on May 12, 2017)

[34] Convention on Biological Diversity, (1992) Article 8 (j).

[35] Loli Frater, "*Protecting Indigenous Knowledge: The Role of the Convention on Biodiversity and Intellectual Property Rights*",16, (2009).

[36] Protecting the Indigenous Knowledge of Biodiversity (India) *available at http://genecampaign.org/wp-content/uploads/2014/Protecting/the/indigenous/knowledge/of/biodiversity/india* (last visited on 12December, 2017).

Food and Agriculture (ITPGRFA) popularly known as the International Seed Treaty."[37] This treaty makes various references, albeit often indirectly, to agricultural TK. [38] For Instance, under Art 5(c) Contracting Parties must "promote and support, as suitable, farmers and local communities efforts to manage and conserve on farm their plant genetic resources for food and agriculture".[39] Another indirect reference to TK is made under Art 5 (d) according to which Contacting Parties have to "Promote in situ conservation of wild crop relatives and wild plants for food production, including in protected areas, by supporting, inter alia, the efforts of indigenous and local communities"[40]. Finally, Art 9, speaks about farmers rights, the crucial importance of farmer's local communities to conserve and develop plant genetic resources, while at paragraph 2 (a) it binds Contracting Parties to take measures to protect and promote the TK regarding plant genetic resources for food and agriculture. Though, it does not protect TK per se but only when related to genetic resources for food and agriculture.

Another agreement is the UN Convention to Combat Desertification (hereafter referred to as UNCCO) adopted in 1994. This treaty provides under Art 16(g), that the parties shall ensure adequate protection for TK as well as provide appropriate return for it. Art 17(c) states that financial benefits descending from the exploitation of TK has to be attributes to the owners of such knowledge. It is, therefore, crucial to notice that TK holders are vested in ownership. Finally under Art 18, lays that TK has to be collected into databases

[37]International Treaty on Plant Genetic Resources for Food and Agriculture, (adopted 3 November 2001) ITPGRAFA *available at http://www.fao.org/cgrfa/cgrfa-about/cgrfa/011/i0510e/i0510e.pdf (*last visited on May 20, 2017)

[38]Gerald Moore and Witold Tymowski, "*Explanatory Guide to the International Treaty on Plant Genetic Resources for Food and Agriculture*, IUCN(2005)

[39] The role of traditional knowledge and access to genetic resources in biodiversity conservation in Southeast Asia, *available at https://link.springer.com/article/10.1007/s10531-010-9816* (last visited on December11, 2017).

[40] *Ibid*

and the content of these is the actual object of ownership. Pires de Carvolho has interestingly pointed out that the UNCCO seems to contain a miniature of a sui generis TK protection system. Such miniature is however, insufficient because the scope of the convention is too narrow and it does provide for a national treatment clause to avoid discriminatory treatment of foreigners.[41] In September 2007, after several years of discussions, the Declaration on the Rights of Indigenous Peoples (hereafter referred to as UNDRIP) was adopted by UN General Assembly. This non-binding document sets out the individual and collective rights of indigenous peoples, as well their rights to culture, identity, language and other issues. It also laid importance on the rights of indigenous peoples to uphold and build up their own institutions, cultures and traditions, and to keep development of their own needs and aspirations to pursue their growth. Many articles of the Declaration mention TK and TCEs in various forms.

The articles under the Declaration shows how the terminology "TK" has become standard in international law and also mention how TK and TECs emphasizes the continuity and the proximity, rather than the clear distinction between the two concepts and lastly also recognizes that TK can be object of IP protection.

The World Intellectual Property Organization (hereafter referred to as WIPO) was established "in 1967, to encourage the activities that were creative, the intellectual property protection all over the world and to maintain administrative cooperation among the Unions".[42] "WIPO has worked on the issue of folklore together with the United

[41]Nuno Peres de Carvalho, "*From the Shaman's Hut to the Patent Office: A Road Under Construction' in Charles McManis (ed), Biodiversity and the law: Intellectual Property, Biotechnology & Traditional Knowledge*, (Earthscan, 262, 2007).

[42] Convention Establishing the World Intellectual Property Organization (signed 14 July 1967, into force 26 April 1970) art *3 available at http://www.wipo.int/treaties/en/text.jsp?file_id=283854* (last visited on 20 May 2017).

Nations Educational, Scientific and Cultural Organization (hereafter referred to as UNESCO)"[43]. "As a result WIPO/UNESCO Model Provision for National Laws on the Protection of Folklore against Illicit Exploitation and other Prejudicial Action"[44] was adopted and was used as a model by numerous Member States looking for a sui generis protection of folklore.[45] WIPO also worked "an intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore"[46] (hereafter referred to as IGC). It focuses on TK, TCEs and genetic resources in order to develop improved mechanisms of protection. Though much is done by WIPO but the works done are predominantly non-binding and broad soft law. However, its strong connections with other institutions such as UNESCO and World Trade Organization as well as its action aimed at spreading the culture of IP law and researching on all aspects of TK make it a key actor in the development of the concept of TK at international level. World Trade Organization (hereafter referred to as WTO) Law does not addresses the issue of TK. Probably, the only provision applicable by analogy to this matter is Art.39 of "the Agreement on the Trade-Related Aspects of Intellectual Property Rights "[47](hereafter referred to as TRIPs), dedicated to the protection of know how.[48] The Doha

[43] Intellectual Property Needs and Expectations of Traditional Knowledge Holders, *available at http://www.wipo.int/edocs/pubdocs/en/tk/768/wipo_pub_768.pdf* (last visited on December 12,2017)
[44] *Ibid.*
[45] Supra note 21.
[46] Rights and Protection Mechanisms For Traditional Knowledge Holders In India, *available at http://jcil.lsyndicate.com/wp-content/uploads/2017/06/Palada-sashwat.pdf* (last visited at November 12,2017), Traditional Knowledge and Intellectual Property-Background Brief *available at http://www.wipo.int/pressroom/en/briefs/tk_ip.html* (last visited on December 12,2017)
[47] Practical Implication of Intellectual Property Law in Developing States such as Pakistan and role of International Arbitration Law in Disputed Cases, *available at https://www.duo.uio.no/handle/10852/54555* (last visited at December 13,2017).
[48]Supra note 21

Declaration[49], approved in 2001 the agenda for a future reform of WTO law, which provides that work in the TRIPs Council on implementation issues should cover the "relationship between the TRIPs Agreement and the UN Convention on Biological Diversity, the protection of traditional knowledge and folklore and other relevant new developments that member governments raise"[50]. Though, the importance of traditional knowledge and the local communities holding such knowledge is identified but international system for protection of TK is still missing.

2.5 Evolution of Biopiracy

The word 'biopiracy' was coined by the North American advocacy group, Action Group on Erosion, Technology and Concentration (hereafter referred to as ETC), also known as Rural Advancement Foundation International, to refer to the commercial use of biological resources or associated TK from developing countries which are uncompensated and calming patents by corporations based on such resources or knowledge.[51] The issue of biopiracy is not new. The piracy of bioresources has a long history of thousands of years. "3500 years ago the Egyptian rulers would bring plants home after their military expeditions. There were no rules regarding the taking of specimens at that time most of the Botanists did the same without any consequence. Rubber trees for the Royal Botanical Gardens was obtained from Brazil and planted in South East Asia. Cinchona seeds were taken from Bolivia, even violating Bolivian law. Richard Shultes during his mid-twentieth century adventures took thousands of voucher specimens of medicinal

[49] Traditional Knowledge, *available at https://en.m.wikipedia.org/wiki/Traditional_Knowledge* (last visited on December 12,2017)
[50] Supra note 50.
[51] Graham Dutfield, "Bioprospecting: Legitimate Research or 'Biopiracy'?" *available at http://www.scidev.net ,* (last visited on May 20, 2017).

plants from shamans, many of which had never previously been identified taxonomically."[52] There were many instances where the people would take away the biological resources that would interest them. None of these famous collecting trips was challenged on any legal grounds whatsoever. It is essential to look closer at the historical events that lead to the emergence of biopiracy issue and also the controversy that surrounds it. Two historical advancements are essential to understand the biopiracy discussion. First is the growth of Intellectual Property system which was the result of globalization especially through the WTO Agreement on TRIPs. Secondly, "the CBD under which biological resources has been regarded as a product".[53]

The biological life forms were excluded from patentability until the 1930s. IP protection was not awarded to plant varieties. By 1930s the developed countries started the method of crossbreeding plants to produce a hybrid. Seed companies also started the use of their increasing work to gain plant breeders' rights legislation.[54] US enacted the Plant Patent Act in 1930, which permitted patenting the phenotype i.e. for asexually reproduced plants. "The Plant Variety Protection Act made intellectual property protection for varieties that were novel, unusual, reliable and stable".[55] After this the area of patent expanded and due to which even the seeds came under the purview of patentability but only under certain conditions.[56] It was only after the modern methods of plant breeding

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[52] Michael A. Gollin, "Biopiracy: The Legal Perspective," *available at http:/ /www. action bioscience. org/ biodiversity / gollin.html,* (last visited on May 10, 2017).

[53] C. Hamilton, "*Biodiversity, Biopiracy and Benefits: What allegations of Biopiracy tell us about Intellectual Property." Developing World Bioethics*, 159, (Vol. 6(3), 2006).

[54] J. R. Kloppenburg, "*Seeds, Sovereignty, and the Vía Campesina: Plants, Property, and the Promise of Open Source Biology*", Paper prepared for the Workshop on Food Sovereignty University of Saskatchewan, 4, (2008)

[55] K. Aoki, "*Food Forethought: Intergenerational Equity and Global Food Supply? Past, Present and Future*", 425, (*Wisconsin Law Review*,2011).

[56] E.K., "*Northand South: The WTO, TRIPS, and the Scourge of Biopiracy*", *Tulsa Journal of Comparative and International Law*, 288 (2003-2004).

the patent protection was regarded as an efficient method for the security of newly developed plant varieties. The non-obviousness requirement of patent protection was not meet as crossbreeding plants were quite apparent method to any farmer. Plant breeding was brought to laboratories through modern biotechnology. With the widespread importance of patent protection to plant reproduction methods and the products that was the outcome grew the significance of patents in plant variety protection.[57]

"International research gene banks"[58] had started to preserve plant genetic resources in the form of raw germplasm to carter samples of the materials for agriculture, research and plant breeding purposes in mid-twentieth century. With the growing importance "these gene-banks became part of the International Agricultural Research Centers and the Consultative Group on International Agricultural Research (CGIAR)".[59] With the help of the research of the Consultative Group the areas of food safety and scarcity suppression was taken care in developing countries. With this there was a celebration of new era of plant ownership. Coming from a period where plant germplasm was generously exchanged and there were individual ownership over rights over plant life, with rapid globalization the gene banks and companies started claiming legal protection for the outcome of their research. Intellectual property rights for plant genetic resources were internationally acknowledgment of the 1961 by the "International Convention for the Protection of New Varieties of Plants"[60] (hereafter referred to as UPOV Convention).

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[57] M. Blakeney, "*International Proposals to Regulate Intellectual Property Rights in Plant Genetic Resources*" in R. E.Evenson and V. Santaniello (eds.), *The Regulation of Agricultural Biotechnology*,41, (Oxford shire, CABI, 2004), .

[58] Research gene banks that preserved plant genetic resources in the form of raw germplasm to carter samples of the materials for agriculture, research and plant breeding purposes.

[59] D. F. Robinson, "*Confronting Biopiracy: Challenges, Cases and International Debates"*, Abingdon,(Earthscan, 2010) L. R. Helfer, "*Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Law making*",28, (*the Yale Journal of International Law*, Vol. 29(1),2004).

[60] The UPOV convention laid down a structure for protection of intellectual property of plant varieties.

The convention laid down a structure for protection of intellectual property of plant varieties in this way the 'plant breeders' rights' (hereafter referred to as PBRs) was recognized. PBRs were awarded to intentionally breed of new plant varieties. Though PBRs are easier to be obtained but they are weak form of IPR Protection in comparison to the protection that a patent offers. The UPOV Convention was at first for the improvement of industrialized countries where plant breeders were strong.[61]

In 1983 the UN Food and Agriculture Organization (hereafter referred to as FAO) adopted the International Undertaking on Plant Genetic Resources (the Undertaking), which was a non-binding agreement that dealt with the preservation and business of plant resources for food and agriculture purposes. The debate as to whether plant germplasm was to be regarded as a 'common heritage of mankind' was motivated by agreement.[62] "The Undertaking formed the Commission on Genetic Resources for Food and Agriculture. Issues related to plant genetic resources was dealt by the Commission which was the only permanent forum"[63]. It provided a place for government negotiations and talks regarding biological diversity that were important agriculture activity and food security.[64] The Undertaking was concerned with the 'common heritage' principle. In developing countries resources was collected freely, but when sold back by seed companies the seeds varieties developed from these resources were granted patent over it.

[61]K. Raustiala and D. G. Victor, "*The Regime Complex for Plant Genetic Resources",* 286, *International Organization*, , (Vol. 58(2)2004).

[62]Supra note 43.

[63] Food and Agriculture Organization of the United Nations, Commission on Genetic Resources for Food and. Agriculture*, available at http://www.fao.org/nr/cgrfa/cgrfa-about/cgrfa-history/en/* (last visited on May12, 2017)

[64]*Ibid*

This classification blocked intellectual property protection of natural materials.[65] The labeling of plants genetic resources ruined the property rights that breeding companies owned. Due to this reasons the Undertaking was opposed by the US and other European Countries. After some changes and pressuring the International Undertaking was altered and the Agreed Interpretation of the International Undertaking was issued in 1989. The plant breeders' right (as protected under the UPOV Convention) was recognized, but was not well-suited with the International Undertaking. The Resolution 5/89 on farmers' rights was adopted by the Commission simultaneously[66]. The traditional farmers' rights require acknowledgement for the important contribution to the conservation and improvement of plant materials. By adopting the interpretation, the Commission upheld stability among the rights of breeders and the rights of farmers.[67]

1992 UN Convention on Biological Diversity (hereafter referred to as CBD) and the 1994 TRIPs was enacted to reduce the growing tensions between developed and developing countries. The CBD was labeled to as the grand bargain as it tried to find a balance between facilitating access to genetic resources and benefit-sharing. The Convention was important because it gave the nations sovereign rights over the biological resources. The debate of seed wars came into conclusion and as a result biological resources could no longer be seen as common heritage. At the end of Uruguay Round the first multilateral negotiations on intellectual property rights was concluded and the TRIPS Agreement and the establishment of the World Trade Organization (hereafter referred to as WTO) was made.

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[65] Supra note 1

[66] "The history of Farmers' Rights*", available at www.farmersrights.org last visited on 12thMay, 2017 at1:00 p.m*.

[67] L. R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Law making*, 38, (*The Yale Journal of International Law*, Vol. 29(1), (2004).

All WTO members were to implement a minimum level of protection for intellectual property. The topic of biopiracy the regulation on patents was one of the crucial topics. There has been a drastic increase on the protection of intellectual property. With the increase on the importance of technology so was the increase on competition at international level especially with the tool of IPRs. The multinational companies lobbied for the removal and elimination of trade barriers in developing countries to get unrestricted admittance to those markets. Developed countries have supported the TRIPS Agreement as it deals with intellectual property rights of developed countries and free market-access for developing countries.[68] However, developed countries notions of patentability only motivated the previously existing problems concerning IPRs.

Under Article 27 TRIPS Agreement which lays for a minimum standard of patentability and this is one of the most decisive provisions. This Article protects the activities of biopirates hence an important provision regarding the issue of biopiracy. In the landmark decision of Diamond v. Chakrabarty the possibility of patent on a living organism was recognized globally the US Supreme Court decided that the patentee had produced a new bacterium which had markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery was not nature's handiwork, but his own; accordingly it is patentable subject matter under sec 101.

In the Ex parte Hibberd case the US Patent Court upheld a patent granted for an entire corn plant, including the seed making the farmers legally obliged to buy new seed every year instead of replanting seed generated by their own plants which they commonly practiced. Patent on living organism were allowed only if certain requirements were

[68]The Pharmaceutical Industry and the Patent System, *available at https://users.wfu.edu (*last visited on March 12 2017).

fulfilled. It was at this time that the discourse of biopiracy emerged. There was an agitation from activists from all over the world against the TRIPs Agreement as it heavily favored the idea of industrialized countries. The NGO's of developing countries, started to campaign against biopiracy e.g. 'Neem campaign'. In the 1990s the first biopiracy cases were tried in court as activists challenged patents of multinational companies. Prior to the Convention of Biological Diversity, 1992, the living resources were regarded as 'common heritage of mankind'. The researcher could, without any legal formalities, arrive at a field site, collect samples of plants, microbes, animals etc., and take them home. There was no applicable law to regulate as to what one can and cannot take from nature. As common resources, researcher's private companies could take and use any resource without having any justification or compensation. This led to steady loss of common peoples' control over their own common natural resources. This has been going on for centuries. It is a story of continuous, ongoing exploitation.

CHAPTER 3

LEGAL FRAMEWORK FOR PROTECTION OF TRADITIONAL KNOWLEDGE: INTERNATIONAL AND NATIONAL LEVEL

The main topic of international debate is what can be a better option for providing protection to TK, either an established IPRs system or through an alternative sui generis system.[69] Traditional knowledge, being 'knowledge' it is important to seek its protection under the rules and principles of intellectual property.[70] As the western impression focuses on the principles that every person has a moral right to control the products of his or her labour or creativity so under this grounds TK should also be protected.[71] Intellectual property rights for TK have been recognized from a natural right based perspective on the basis of a system of entitlement theory[72] and theories of self-development as value of individual autonomy.[73] There are many methods that are proposed for protection of TK which includes a system of traditional resources rights,[74] a system of discoverer's rights,[75] a system of identification of source materials,[76] and a

[69] *WIPO/GRTKF/IC/7/6, The Protection of Traditional Knowledge: Outline of Policy options and Legal elements, available at www.wipo.int* (last visited on May 20, 2017)

[70]Hanns Ullrich, *Traditional Knowledge, Biodiversity, Benefit Sharing and the Patent System Romantic v. Economics*, 4(, European University Institute, Badia Fiesolana, Italy, 2005).

[71]Srividhya Ragavan, *Protection of Traditional Knowledge*, (Minnesota Intellectual Property Law Review, Vol. 2, No. 2, 2001).

[72] Anthony J. Stenson and Tim S. Gray, *The Politics of Genetic resource Control, (*Macmillan Press Ltd., London, 1999).

[73] Ibid.

[74]Darell A. Posey, *Traditional Resource Rights: International Instruments for Promotion and Compensation for Indigenous Peoples and Local Communities, (*IUCN, Gland, Switzerland, 1996).

[75] Michael A Gollin, *An International Property Rights Framework for Biodiversity Prospecting in Walter V. Reid et. al., Biodiversity Prospecting: Using Genetic Resources for Sustainable Development, (*World Resources Institute, Washington, 1993).

[76]Madhav Gadgil and P. Devasia, *Intellectual Property Rights and Biological Resources: Specifying Geographical Origins and Prior Knowledge of Uses,* 69, (Current Science, Vol. 8, 1995).

system that advocates separation of ownership of genetic resources from the ownership of the knowledge itself.

Many authors have put up the advantages and disadvantages for protecting TK within the existing IP laws. There are three sets of view which propose that there is an issue of using conventional forms of IPRs for protecting TK the first of these views supports that different form of IPRs should be used to protect TK, while the other is of the view that a particular forms of IPR could be best for protecting TK and the last one is of the view that established forms of IPRs are not appropriate for protecting TK. Though TK has been regarded as important components for sustainable development, conservation process and also for food security of human beings, still the issue of protecting TK is left as it is. In the following pages the various Convections, Agreements, Acts are analyzed to look into possible ways for protection of TK.

3.1 PROTECTION OF TRADITIONAL KNOWLEDGE AT INTERNATIONAL LEVEL

Many International Conventions and Agreements address the subject of TK, such as the Trade Related aspects of "Intellectual Property Rights (TRIPs)[77], Convention on Biological Diversity (CBD)"[78], the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR)[79], The United Nations Conference on Trade and Development[80] (UNCTAD), the U.N. "Educational Scientific and Cultural Organization

[77] The Trade Related aspects of Intellectual Property Rights, 1994
[78] Supra note 50.
[79] The International Treaty on Plant Genetic Resources for Food and Agriculture,2001
[80] The United Nations Conference on Trade and Development,1964

(UNESCO)"[81], World Intellectual Property Organization (WIPO)"[82] etc. Though there are many Conventions and Agreements that highlight the importance of TK but there is still no specific clause or particular legislation that lay down the protection measures that can be provided to TK.

3.1.2 UNITED NATIONS COMMISSION ON HUMAN RIGHTS (1964)

United Nations Commission on Human Rights (hereafter referred to as UNCHR) had established a working group for the Draft Declaration on the Rights and Indigenous People, the Draft Declaration dealt with the rights of indigenous people in areas such as self determination, culture and language, education, health, housing, employment, land and resources, environment and development, intellectual and cultural property, indigenous law and treaties and agreements with governments.[83] Due to the effort put up by the working committee under UNCHR the draft was adopted by the General Assembly on 13th September 2007. Though at first many countries opposed it but recently they have reversed their position and are now the member of the declaration. "Under Article 29 of the Declaration the Indigenous peoples have rights of full ownership, power and protection of their cultural and intellectual property and also free to develop, protect and control their technologies, cultural manifestations including human and other genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs and ritual and performing arts".[84] The tension between IP protection and the protection of TK especially of those knowledge

[81] Supra note 50.
[82] Supra note 44.
[83] Traditional Knowledge *available at www.med.govt.nzlbuslt/int-prop/traditionalknowledge/ fact-sheets/fact-sheets-08.html* (last visited on May 23,2017).
[84] *Ibid*

that were used without getting prior consent of the people which rejected them the compensation that they would be entitled to. For the survival, well-being and dignity of indigenous peoples of the world and it elaborates on existing human rights standards and fundamental freedom Declaration established a universal framework of minimum standards.[85]

3.1.2. "THE UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT" (UNCTAD) (1964)[86]

The United Nations Conference on Trade and Development (hereafter referred as UNCTAD) has a long history within the United Nations as the focal point for the integrated treatment of trade and development, together with related issues in the areas of investment, finance, technology, enterprise development and sustainable development. UNCTAD has played an important role in IPR matters and has in particular conducted fundamental work relating to IP and development including the relationship between IP and technology transfer as well as competition policy. It also played an important role during the negotiations between the UN and the WIPO that made the latter a specialized agency of the UN. But the time TRIPs was being adopted the role of UNCTAD's on IP was somewhat limited. This was done knowingly to sideline UNCTAD on these issues because it played an important role to provide a forum for developing countries to come up with strategies and also to analyze work which demonstrated grave negative outcome

[85] United Nations Declaration on the Rights of Indigenous Peoples *available at https:// www.un.org (*last visited on May 23, 2017).
[86] Traditional Knowledge, intellectual Property, And Indigenous Culture: An Introduction, *available at http://www.peteryu.com/tk.pfd* (last visited on November 15, 2017)

for technology advancement and related principles that arose from the existing IP regimes.[87]

UNCTAD has continued to be involved in intellectual property work in the context of other policy areas in collaboration with other organizations. One of the significant works that UNCTAD has been working on is related to transfer of technology and the work on Ecommerce mainly concerned with open source software and related issues. It has also collaborated in the last few years and conducted a quite successful joint building project on intellectual property rights and sustainable development with the International Centre for Trade and Sustainable Development (ICTSD) which is responsible for a large number of research works on intellectual property and development as well as meetings and conferences.

Therefore it is inevitable to work for preparing UNCTAD XI under which the developing countries can make effort to increase the task of UNCTAD related to IP and to undertake analysis on strengthening the development dimension in international intellectual property rule-making, including effective transfer of technology to developing countries, protection of TK , genetic resources, and folklore. On the other hand, it is also clear that the opposition by the United States and other developed countries to the inclusion of intellectual property in the mandate of UNCTAD to continue.

An expert meeting was held by the UNCTAD in November 2000 on Systems and National Experience for Protecting Traditional Knowledge, innovations and Practices. More than 80 countries participated in the meeting and were represented by representatives of the government, indigenous groups, Inter Governmental Organizations (IGOs), academics circles, NGOs, private companies and international agencies. The

[87] Peter Drahos & John Braithwaite, *The Globalization of Regulation*,103-107,(Vol9, 2001)

Meeting's outcome which reflected the diversity was taken up by the UNCTAD Commission on Trade in Goods and Services and Commodities. Many recommendations were laid down they were to raise awareness about protection of TK among the common people, to maintain the innovation possibility of local and indigenous communities so that they can protect their knowledge, to help in documentation process TK and to encourage the commercialization of TK based products.[88] "TK was defined to refer to the knowledge innovations and practice of indigenous and local communities representing traditional life styles as well as indigenous and traditional technologies".[89] Some important features of TK were also laid down:-

- TK was regarded as valuable to all those who depend upon it for their survival and also to modern industry and agriculture and sustainable development.
- A number of TK derived products were internationally sold.
- Biogenic resources and their associated TK gave vital inputs into the markets including pharmaceutical, cosmetics, agriculture, food additives, industrial enzymes, bio-pesticides and personal care.
- There is a significant contribution to modern industry and agriculture by TK.
- By the direct application of TK the farming systems of the world had developed for over 10,000 years
- The development of other products was as possible with the help of TK
- It was difficult to estimate the full value of TK in monetary terms.

[88]UNCTAD Commission on Trade in Goods and Services, *available at http://www.unctad.org/en/special/c1dos5.htm>* (last visited on June 12,2017).
[89] Intellectual Property Rights: Implications for Development, *available at http://www.iprsonline.org/unctad/projectoutputs.htm*. (last visited on June 12, 2017).
A Review of UK Patent Activity for Genetic Resources and associate Traditional Knowledge available at http://randd.defra.gov.uk/Document.aspx?Document=13316_WC1086NagoyageographicalUK_IPGR_Report_2013.pdf

3.1.3. THE WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO) (1970)

WIPO is an international organization consecrated to render worldwide protection of the rights of creators, innovators and owners of intellectual property. WIPO's origin dates back to 1883 in Geneva, Switzerland when the Paris Convention was entered into force and an International Bureau was established to fulfill the administrative tasks. This International Bureau developed over time to be what is known today as WIPO. In 1974, WIPO became a specialized agency of the United Nations and in 1996 WIPO expanded its role into globalized trade by entering into a cooperation agreement with the World Trade Organization[90]. WIPO currently has 191 member states and administers 23 treaties. The 23 treaties administered by the WIPO are divided into three classes:

1. Intellectual Property Treaties that define the internationally agreed basic standards of intellectual property protection; e.g. Paris Convention;
2. Global Protection System Treaties that aim to ensure that one international registration or filing having an effect of the relevant signatory States; e.g. PCT and Budapest Treaty; and
3. Classification Treaties that create systems that organize information concerning inventions into indexed structures to enable easy retrieval; e.g. International Patent Classification (IPC).[91]

"To initiate the protection of intellectual property throughout the world, WIPO encouraged conclusion of new international treaties and the modernization of national

[90] Daniel F. Olejko, "*Charming a Snake: Open Source Strategies for Developing Countries Disillusioned with TRIPs*", (Vol25, 2007). *Available at http://elibrary.law.psu.edu/psilr/vol25/iss4/9.*
[91] WIPO, *available at < http://www.wipo.int.tk/en.>* (last visited on May 12, 2017)

legislations"[92] that would give technical assistance to developing countries and disseminates information to maintains "services for facilitating the obtaining of protection of inventions, marks and industrial designs and promotes other administrative cooperation among member States."[93] As to the administrative cooperation among the Unions, WIPO centralizes the administration of the Unions in the International Bureau in Geneva, which is the secretariat of WIPO, and supervises such administration through its various organs. Economic issues of the member states are ensured through centralization.

WIPO seeks protection of TK by gaining a close cooperation with other international agencies and processes, which would take into account the 'full international context for the protection of TK'. WIPO's International Committee on Intellectual Property and Genetic resources (IGC) conducts "text based negotiations" to achieve effective protection of TK through the conclusion of "international legal instrument on TK". "Along with this, international efforts to protect TK runs across a thicket of legal regimes which deals with environment, indigenous peoples' rights, biodiversity, human rights, food and agriculture."[94]

WIPO has enacted into since January 1, 1996, an Agreement with the World Trade Organization (WTO), which is not a member of the United Nations system of organizations. The Agreement provides for cooperation between the International Bureau of the WIPO and the Secretariat of the WTO in respect of assistance to developing countries, in respect of the notification and collection of the intellectual property laws and regulations of WTO Members, and in respect of the notification of emblems of States and

[92] Supra note 44.
[93] *Ibid*
[94] Tesh Dagne, "*Protecting Traditional Knowledge in International Intellectual Property Law: Imperatives for Protection and choice of Modalities*", 25, (14 J, Marshall Rev. Intell. Prop. L., 2014).

international organizations.[95] In planning and implementing its activities for developing countries, WIPO is guided by the relevant objectives of international cooperation for development, with particular reference to making full use of intellectual property for encouraging domestic creative activity, for facilitating the acquisition of foreign technology and the use of literary and artistic works of foreign origin, and for organizing easier access to the scientific and technological information contained in millions of patent documents. All this should serve the cultural, economic and social development of developing countries. There are many instances where WIPO has openly demanded the need for protection of TK.[96]

3.1. 4. CONVENTION ON BIOLOGICAL DIVERSITY (1992)

"The UN Convention on Biological Diversity (CBD) was signed at Rio de Janerio in June 1992, the main objectives was conservation of biological diversity, sustainably using of its components and the fair and equitable sharing of the benefits that would arise out of the utilization of genetic resources of a particular country."[97]

Article 8 (j) of the CBD is one of the important provisions related to TK.[98] The parties to the CBD are required under Article 8 (j) "to respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional

[95] Understanding The WTO: The Agreements Intellectual property protection and enforcement, *available athttps://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm* (last visited on June 17, 2017).
[96] Ibid
[97] Biopiracy and its impact on Biodiversity:A Citical Analysis With Special Reference To Sri Lanka *available at http://ijbel.com/wp-content/uploads/2014/07/Bio-piracy-And-Its-Impact-On-Bio-diversity---A-Critical-Analysis-With-Special-Reference-To-Sri-Lanka-C.L.Akurugoda.pdf* (last visited on June 12, 2017).
[98] Protection of traditional knowledge a comparative study of India and Bangladesh, *available at sodhganga.inflibnet.ac.in* (last visited on June 14, 2017).

lifestyles relevant for the conservation"[99] and "sustainable use of biological diversity and encourage the equitable sharing of the benefits arising out of the utilization of such knowledge, innovations and practices"[100]. Article15 of CBD deals with provisions regarding access and benefit sharing of genetic resources.[101] It never grant states a property right over genetic resources but only recognizes its right to restrict. "Rather CBD by making the undue restrictions of nations clear, and in order to facilitate the access states that Each Contracting Party shall attempt to generate circumstances to assist access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention."[102]

Article 15 deals with access on biological resources and lays that it should be only granted on mutually agreed terms, Article 15 (4) deals with the provision relating to "prior informed consent of the Contracting Party providing such resources, Article 15(5)" [103]. Under Article 15(7), "Each Contracting Party must take an effective step either legislative, administrative that would lead to sharing in fair and equitable way the results of research and development and the benefits arising that would arise out of the commercial exploitation. Such sharing shall be upon mutually agreed terms"[104]. The CBD constituted Expert panel on Access to Genetic resources and benefit sharing concluded in October 1999. Secretariat of the Convention on Biological Diversity,

[99] Indigenous Traditional Knowledge *available at https://lop.parl.ca/* (last visited on December 12,2017)
[100] Indigenous Peoples and Biodiversity in The Arctic, *available at https://www.arcticbiodiversity.is/the-report/chapters/indigenous/peoples/and/biodiversity/in/the/Arctic* (last visited on November 16,2017)
[101] Convention on Biological Diversity, (1992), Article15 (1)
[102] Supra note 44.
[103] Biopiracy And Its Impact on Bio Diversity-A Critical Analysis With special Reference to Sri Lanka *available at http://ijbel.com/wp-content/uploads/2024/07/Bio-Piracy-And-Its-Impact-On-BioDiversity---A-Critical-Analysis-With-Special-Reference-To-Sri-Lanka-C.L.Akurugoda.pdf* (last Visited on December 23,2017)
[104] The Relationship between TRIPS and the Technology Transfer Provisions under the Convention On Biological Diversity: Can the Parties to the CBD Implement the technology transfer provisions without contravening TRIPs? *Available at https://www.duo.uio.no/handle/10852/20803*

1999[105] lay down that "the degree of legislative simplicity in countries providing genetic resources would increase to the extent that countries and organizations receiving genetic resources take the legislative, administrative or policy measures to offer security to providers that these resources are utilized in accordance with the terms of the Convention"

"The CBD recognizes both the dependency of indigenous people on biodiversity and also their unique role in conserving life in earth."[106] "It is for this reason that the convention provides that the parties have undertaken to respect, preserve and maintain the knowledge, innovations and practices of indigenous and local communities relevant for the conservation of biodiversity"[107]. "More emphasize is also laid to promote their wider application with the approval of knowledge holders and to encourage equitable sharing of benefits arising out of the use of biodiversity."[108]

3.1. 5. THE TRIPS AGREEMENT

The TRIPS Agreements is a product of the World Trade Organization, an organization established by industrialized nations to promote free trade under a global trading system[109]. The objective of TRIPS is to encourage the constant evolution of ideas by providing ample protection to intellectual property rights owners and rewarding their innovativeness and ingenuity.[110] The TRIPS agreement is recognized as an "impressive" document for its "comprehensive scope and coverage," leading some to recognize it as

[105] Secretariat of the Convention on Biological Diversity(SCBD) 1999, Report of the panel of Experts on Access and Benefit - Sharing, UNEP/CBD/COP/5/8, Monreal
[106] Supra note 17

[107] *Ibid*
[108] Supra note 17.
[109] Marcia E. DeGeer, *Biopiracy: The Appropriation of Indigenous Peoples' Cultural Knowledge, 180, (* 9 NEW ENG. J. INT'L & COMP. L. ANN. 179, 180 2003)
[110] *Ibid*

the "most important multilateral instrument in this field."[111] "The concept of private rights is incorporated in TRIPS under Article 28 whereby, a patent confers exclusive rights on its owner to avoid third parties from developing, using, offering for sale, marketing or importing the product that is patented."[112] IP owners are taken to be the natural or legal persons such as corporations and institutions .This system of exclusive and private rights clashes with the traditional social and economic system in which local communities make use of and develop biodiversity, including crops and medicinal plants. Seeds and knowledge on crop varieties and medicinal plants are usually freely exchanged within the community. Additionally, as part of the WTO, the TRIPS agreement is tailored to the needs of industrialized nations this puts pressure on developing countries that wish to conduct trade with these nations to conform to TRIPS standards.[113] Article 27 of the TRIPS agreement lays out the requirements for patentability. Paragraph (1) of Article 27 lays down that "patents are awarded to any inventions products or processes, in all fields of technology, but the inventions must be new, involve an inventive step and are capable of industrial application."[114]Article 27 clarifies that member states may interpret "inventive step" and "capable of industrial application" to refer to the more familiar patent terminology of "non-obvious" and "useful."[115] These broad standards establish "a general principle of eligibility" for patents.[116]

[111] Gervais, "*The TRIPS Agreement: Drafting History and Analysis*", 2d Ed. 220 (2003).
[112] Bioprospecting for blue gold in the high seas: Regulatory options for access and benefit sharing, *available at https://www.duo.uio.no/handle/10852/35087* (last visited on December 10,2017)
[113]Supra note 23
[114]Intellectual Property Rights the resourcefulness of Third World countries *available at894a018f-9e21-4256-835e-3eba9576fa96* (last visited on Decemberr 1,2017).
[115] *Ibid*
[116]*Supra* note 25

TRIPs does not specifically mention TK as a protectable subject matter under its ambit because it does not establish a universal rule for novelty, but it does not expressly debar or prohibit protection to TK as a form of intellectual property rights. The IPR system as envisaged under TRIPS has two main consequences on the one hand, if TK innovations fulfill the criteria for protection under existing categories of IP rights they are not excluded from the purview of the Agreement and on the other hand, there is no recognition of the special nature of TK under TRIPS.

3.1.5 TOOLS OPTED TO PROTECT THE TRADITIONAL KNOWLEDGE UNDER TRIPS

To address the problems that are faced by the traditional knowledge holders, many international conventions and agreements has been developed. But the issue regarding the protection of TK is still not met. One of the important developments is the TRIPs agreement where different types of Intellectual property rights are given and protected. But to gain IP protection there are certain conditions that are to be fulfilled. It other words, TK must meet the statutory criteria stipulated for various forms of IPRs under the relevant statutes.

3.1.5. (a) PATENT

Many contend that TK can be protected under Patent, but there are certain criteria's that needs to be fulfilled to avail patent rights, they are (a) novelty, (b) inventive step and (c) industrial utility. "Any inventions, whether products or process but if novel, capable of industrial application and involving inventive step would be granted with patent rights

under the TRIPs Agreement".[117] Likewise, the Indian Patent Act, 1970 defines 'invention' as a new "product or process which engages an original step and is able of manufacturing use".[118] If the requirements are fulfilled the inventors, innovators gets the legal monopoly over the use, production and sale for a specific period of time (usually about 20 years). All inventions are not patentable though they may otherwise satisfy all the conditions of patentability. A patent will be granted for an invention if the subject matter is open for patenting, or to put it in other words, if the invention does not fall under an excluded category. Therefore, the question whether there is an invention is a question of fact in each case.[119]A combined reading of the sections under the Patent Act[120] reiterates that there can be no patent protection in the country on TK *per se* or which involves traditionally known component or components. Novelty is the *sine quo non* of patents. Though, the Indian Patent Act, 1970 does not define the term 'novelty', the Patents (Amendment) Act, 2005 the concept of novelty is delineated the term new

[117]Sybren Raaijmakers, "*Intellectual Property Rights*", available at www.*894a018f-9e21-4256-835e-3eba9576fa96.doc* (last visited on December 14,2017). Section 5: Article 27. 1 of TRIPS runs as follows: Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However,

Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

[118] Supra note 115.

[119] J. K. Das, *Intellectual Property Rights*, Kamala Law House, Kolkata, 258, (2008).

[120] The Indian Patent Act, 1970

invention under section 2(l) is defined as "invention that are novel and include any invention that is not published in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter must not be known by the public and should not form part of prior art of any state". Novelty lies in the non-disclosure of the invention to the public. It presupposes that there should be no prior knowledge of the invention with the public. It requires the secrecy of the information for the purpose of claiming novelty. An invention may be anticipated either by (a) prior publication or by (b) prior use. Section 13 of the Act requires the patent examiners to conduct search for anticipation.[121]

The prior publication gives the information that the patent claims already filed before the authorities anywhere in the world or the presence of the information in any publication or document that is available for public examination irrespective of whether any member of

[121]Section 13 reads as under: Search for Anticipation by previous publication and by prior claim. TheExaminer to whom an application for a patent is referred under section 12 shall make investigation for the purpose of ascertaining whether the invention so far as claimed in any claim of the complete specification –

(1) has been anticipated by publication before the date of filing of the applicant's complete specification in any specification filed in pursuance of an application for a patent made in India and dated on or after the 1st day of January, 1912;

(2) is claimed in any claim of any other complete specification published on or after the date of filing of the applicant's complete specification, being a specification filed in pursuance of an application for a patent made in India and dated before or claiming the priority date earlier than that date.

(2) The Examiner shall, in addition, make such investigation as the Controller may direct for the purpose of ascertaining whether the invention, so far as claimed in any claim of the complete specification, has been anticipated by publication in India or elsewhere in any document other than those mentioned in sub-section

(1) before the date of filing of the applicant's complete specification.

(3) Where a complete specification is amended under the provisions of this Act before it has been accepted, the amended specification shall be examined and investigated in like manner as the original specification.

(4) The examination and investigations required under section 12 and this section shall not be deemed in any way to warrant the validity of any patent, and no liability shall be incurred by the Central Government or any officer thereof by reason of, or in connection with, any such examination or investigation or any report or other proceedings consequent thereon.

the public including the person claiming the invention has read it or not.[122] The prior use is the use through which the person gives information to other people that such knowledge is already in use and known by the public.[123] That is to say that if the product based on the invention is already in the market or in case of process it is in use for the manufacture of a product.[124]

When TK is examined in the light of patent requirements, it is clear that almost every categories of TK are in the public domain. Thus, the requirement of novelty is defeated in as much as the common public is aware of the information. With reference to a particular TK there is no doubt that at least a particular segment of the local or indigenous community is aware of the information and in most cases the knowledge is in the continuous use of the community. On the basis of the statutory requirement of novelty one can categorically argue that majority of the existing products and processes based on TK will not satisfy the test of novelty. The lack of novelty will disqualify the products based on the knowledge to be treated as invention for the purpose of patent protection. The second requirement for obtaining a patent is 'inventive step'. This is a new term substituted for the old term of non-obviousness. The inventive step is defined "as a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art."[125] Sections 25(1) (e) and 25(2) (e) state that a patent can be opposed on the ground of lack of inventiveness. Section 64(f) further makes

[122]Lalubhai Chakubhai Jariwalv Chimanlal & Co., AIR 1936 Bom. 99 and Monsanto Company v. Coramandal Indug Products (P) Ltd., AIR 1986 SC 712

[123]Automatic Coil Winder etc. Co. Ltd. v. Taylor Electrical Instruments Ltd., [1944] RPC 41.

[124]Indian Vacuum Brake Co. Ltd. v. E. S. Laurd, AIR 1926 Cal. 152.

[125] The Patent Act, 1970 as inserted by the Patent Amendment Act,(2005) Section 2 (ja).

it a ground for revocation.[126] The requirement of inventive step is to demonstrate that the invention is the creation of the individual or individuals claiming monopoly. This is to ensure that substantial intellectual labour of the inventor is involved in the creation of the new invention. It is a question of law based on underlying facts.[127] So the test applied by the courts is to examine whether there is any application of inventive faculty of the inventor.[128] Correct assessment of inventiveness requires assessment not by reference to specific single items of prior art but by reference to the entire knowledge resulting from the entire prior art for the ordinary expert in the art.

One of the significant features of the TK is the fact of it being passed on to the present generation by the previous one. This gives a *prima facie* impression that the present custodians of this knowledge are not the creators but only the successors in interest of the earlier creators. It neither involves technical advance as compared to the existing knowledge or any economic significance. It is, thus, obvious that the present claimants have not contributed any independent thought, ingenuity or skill to establish a valid patent claim. In this context the existing TK will remain as a prior art rather than a new art for patent protection. It is obvious to a person skilled in the art. This also negates the second condition for claiming patent for TK.

[126]The Patent Act, (1970) Section 64 (f), provides that a patent can be revoked on the ground that that the invention so far as claimed in any claim of the complete specification is obvious or does not involve any inventive step, having regard to what was publicly known or publicly used in India or what was published in India or elsewhere before the priority date of the claim.

[127]*Ibid*.

[128]M/s. Bishwanath Prasad Radhe Shyam v. M/s. Hindustan Metal Industries, AIR 1982 SC 1444; Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd., [1985] R.P.C. 59.

3.1.5. (b) TRADEMARK

Trademarks are a way of protecting the use of marks, words, phrases, symbols, designs, or any combination of these associated with goods or service. Once a trademark is established, it can be used to identify and differentiate similar goods and services. Trademarks can be used as a mechanism for the protection of some forms of indigenous art. The trademark can be used to refer to a tribe, an artist, or a combination of both. It has the flexibility to be used for all forms of folk art, including folk medicines. There are countries which provide collective trademarks and certification trademarks, the use of which allows for control of the quality of goods sold by members of the collective community.[129] Such use is frequently recommended and actually followed in practice. Indigenous groups can get registration of trademarks and sell their products using this symbol to distinguish their brand and ensure its unique quality. Thus, reputation of TK can be safeguarded to a certain extent by trademark system though it will not protect the substance of such knowledge.[130] It will assure defensive protection against acts of passing off non- genuine products or services. Such use of mark can certainly establish product fidelity and protect against loss of reputation resulting from the use of the designation of TK for derivatives products. It is very much like the use of trademarks even after the expiration of patents, particularly in case of pharmaceutical patents, to prolong product fidelity. In the event, if a patent prohibits the indigenous community from selling the product, they could register the trademark and subsequently license out the use of the trademark in order to allow companies to ensure authenticity. Existing procedures could

[129]Article 64 et seq. Council Regulation 40/94 December 20, 1993, on the Community Mark, OJEC 1994 L 11, 1, as amended by OJEC 2004 L 23, 88.
[130]Intellectual Property and Traditional Knowledge-WIPO, *available at www.wipo.int (*last visited on July 25, 2017)

be performed on products and approved by a community as a method of adding value to a product with the potential to collect royalties on the products sold.

3.1.5. (c) GEOGRAPHICAL INDICATION

The TRIPS Agreement defines "geographical indication" in Article 22.1, as any sign that recognize a product or goods as originating in the territory of a Member, a region or locality in that territory, where a given superiority, status or other characteristic identifies its geographical origin.

Some important International Agreements on Geographical Indications are listed below;

• "The Paris Convention"[131];

• "The Madrid Agreement for the Repression of False and Deceptive Indications of Source on Goods, 1891"[132];

• "The Lisbon Agreement especially the protection of Appellations of Origin and their International Registration, 1979"[133].

Like trademarks, when associated with a product, it positively attributes a known quality to the product that is associated with a specific geographical location. The use of geographical indication is not permitted in respect of goods produced in region other than that specific geographical area. A geographical indication does not require any element of novelty, originality or inventiveness since it specifically addresses goods produced or manufactured in a specific region or locality. Like trademarks, geographical indications can also be used by a particular tribe or indigenous group to identify the tribe or group to the consumers. It can echo the communal sense as it is mainly judged by its location and

[131] Supra note 44.
[132] *Ibid*
[133] *ibid*

method of production. It can be registered in the name of any association or group of people. It will thus indicate the place of origin and assure its unique characteristic and quality. A number of products are developed from various regions and it is because of traditional processes and knowledge carried out by one or more communities or group in a given region.[134] The marketable price of natural, customary and skill products of all kinds are improved by Geographical indications and appellations of origin. The special characteristics of those products can be a symbol through which the products source can be identified. To give improved protection to the economic interests of the local communities and regions of source of the products improved utilization and encouragement of conventional geographical indications must be done.[135] Hence, the producers in the relevant region, indigenous or local community, can associate together to develop, maintain, register and protect their products bearing the geographical indication.[136]

3.5.1(d) UNDISCLOSED INFORMATION OR TRADE SECRETS

Undisclosed information is a subject matter of IPR under the TRIPS agreement.[137] This branch of law protects undisclosed knowledge through secrecy and access agreements, which may also involve paying royalties to knowledge holders for access to and the use of their knowledge. Three elements are required for knowledge to be classified as a trade secret, the knowledge must have commercial value, the knowledge must not be in the

[134]Case of Aranmula Mirror of Kerala*, available at www.thehindu.com/ news/national/kerela/mirrored-in-fake-imitations/article7932025.ece* (last visited on June 12, 2017)
[135] The Economics of Intellectual Property, *available at www.wipo.int>edocs>wipo_pub_1012* (last visited on July 20, 2017)
[136]*Ibid*
[137] The TRIPS, (1994) Article 39 .

public domain, and the knowledge is subject to reasonable efforts to maintain secrecy. A trade secret is only enforceable as long as it remains a secret. The main object is to legally stop the information under the control of a person from being disclosed to, acquired by, or used by others without consent, in a manner contrary to honest commercial practices. But once the knowledge is released to the public, this option no longer exists.

This area of law is concerned with secrets of all kinds.[138] They may be of personal, technical, commercial or industrial nature. It covers any pattern, device, compilation, method, and technique, recipes for food and beverages or process that gives a competitive advantage. It can be extended to protect potential ideas too. Since it covers a wide range of information, traditional knowledge that is maintained within a community by individuals or groups can be considered a trade secret. Moreover, undisclosed information is considered as a subset of traditional knowledge by WIPO.[139] Trade secrets have no legal protection except in cases of "breach of confidence and other acts contrary to honest commercial practices."[140] This means that one must be able to prove some form of malicious intent on the part of a contracting party as the cause for a trade secret's diffusion to the public in order to be compensated for the loss of secrecy. As per Megarry J., the doctrine of confidence requires three elements:[141]

- The information must have necessary element of confidence about it

[138] David Bainbridge, *Intellectual Property*, 285, (4th ed., Pitman Publishing, London, 1999).
[139] WIPO Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge (1998-1999) published in April 2001.
[140] Trading into the Future: the Introduction to the WTO, Intellectual Property Protection and Enforcement, World Trade Organization, August 2002 *available at http://www.wto.org/ english/thewto_e/whatis_e/tif_e/agrm6_e.htm ,* (last visited on May 16, 2017)
[141] Coco v. A N Clark (Engineers) Ltd., (1969) RPC 41.

- ii. The information must have been in circumstances importing an obligation of confidence, and
- iii. There must be an unauthorized use of that information to the detriment of the party communicating it.

Breach of confidence lies in the domain of equity. [142] Being rooted in equity and freed from the straightjacket of statutory interpretation, the law of confidence retains useful flexibility.[143] This flexibly can very well be utilized for protecting traditional innovations, practices and knowledge possessing potential or commercial value.

3.1.6 "INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE (2001)"[144]

"After years of negotiations in the Commission on Genetic Resources for Food and Agriculture, the FAO Conference adopted the International Treaty on Plant Genetic Resources for Food and Agriculture, in November 2001"[145]. The Treaty entered into force in 2004, after forty governments had ratified it. This legally-binding Treaty covers all plant genetic resources relevant for food and agriculture. It is in harmony with the Convention on Biological Diversity.

The Treaty's objectives are the "protection and sparing use of plant genetic resources for food and agriculture purposes and the fair and equitable sharing of benefits resulting from

[142] Duchess of Argyll v. Duke of Argyll, (1967) Ch 303 at 322 and Kitechnology BV v. Unicor GmbH Plastmaschinen, (1995) FSR 765.
[143] David Bainbridge, *Intellectual Property*, 293,(Pitman Publishing, London, 1999).
[144]Food and Agriculture Organization, *available at http://www.fao.org/nr/cgrfa* (last visited on December 11,2017)
[145] *Ibid*

their use."[146] The enormous contribution made by farmers and their communities and continuous effort to make to the conservation and development of plant genetic resources is recognized by the treaty. The basis for Farmers' Rights, which include the protection of traditional knowledge, and the right to participate equitably in benefit-sharing and in national decision-making about plant genetic resources. The governments must take up the responsibility for implementing these rights.

3.1.7 "NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION" [147](2010)

It is a supplementary agreement to the CBD it lay down a transparent legal framework with main objective of efficient discharge of the just and unbiased distribution of profit that arise out of the utilization of genetic resources . It establishes more predictable conditions for access to genetic resources, and also helps to ensure that benefits-sharing when genetic resources leave the country, and thus gives an incentives to preserve and sustainably use genetic resources, which in turn enhances the contribution of biodiversity to development and human well-being.

Nagoya Protocol applies to genetic resources that are covered by the CBD, and to the benefits arising from their utilization. The Nagoya Protocol sets out core obligations for

[146] Bioprospecting for blue gold in high seas: Regulatory options for access and benefit-sharing, *available at https://www.duo.uio.no/handle/10852/35087* (last visited on November 14,2017)

[147] A Review of UK Patent Activity for Genetic Resources and associated Traditional /knowledge, *available at http://randd.defra.gov.uk/Document.aspx?Document=13316_WC10NagoyageographicalUK_IPGR_Report_2013.pdf* (last visited on November 12, 2017)

its contracting parties to take initiatives in relation to, benefit sharing and access to genetic resources compliance.

3.2 POSITION OF INDIA IN PROTECTION OF TK

India is a diverse country in every sense. It is one of the "mega diverse" countries under the CBD due to its innumerable genetic resources and associated TK. India holds a diverse biological resources and since ancient times those resources have been a part of the tradition of the people living here. With advancements in technology around world, TK are vulnerable to bio-piracy and other threats. With the view to protecting TK, much legislation has been enacted.

3.2.1 THE PATENT ACT, 1970

India has a much longer experience with patents systems than some European countries because of its colonial past. The Patent Act of 1970 brought about significant changes. It excluded patentability of life forms and specifically the patenting of methods of agriculture and horticulture.[148] The Act specifically mentioned that the general principles governing the use of patents were that:

(a) "patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale"[149]; and

(b) "patentees cannot merely enjoy a monopoly for the importation of the patented article"[150]. The very first initiative for the protection of TK in India was after the amendment Act of 2002. The Patent Act of 1970 does not protect the TK. In 2002 TK got

[148] Patents Act, (1970) Section 3.
[149] *Ibid*
[150] *Ibid.*

some protection. The amended Act shows the concern for the protection of TK. In 2005, India implemented a new patent law in order to comply with the "World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property rights (TRIPs)"[151], creating a large new market for WIPO activities. Western lobbyists have worked to increase understanding in India of the potential economic opportunities in patenting, which is significant for a country that is the leading producer of generic medicines and has a deep supply of biodiversity and TK. Western firms also have fought India's patent law in court to try to weaken provisions giving India the ability to reject patents.

3.2.2. THE WILDLIFE PROTECTION ACT, 1972

"The Wildlife Protection Act was passed by the Indian Parliament in the year 1972 to protect India's wildlife."[152] The act provides for the constitution of a National Board for Wildlife with the Prime Minister as the Chairperson. The National Board promotes the conservation and development of wildlife and forests by such measures as it thinks fit. The act also provides for the constitution of a State Board for Wildlife to advise the state government in matters connected with the protection of wildlife. The act regulates the hunting of wild animals and protection of specified plants. It also empowers the State Government to notify Sanctuaries, National Parks, and Game Reserves. Contravention of provision of the act is punishable with imprisonment from 1 to 7 years and fine up to Rs. 50 lakh depending on the nature of offence. [153] In Sikkim the Forest department plays a

[151] Supra note 50.
[152] Wild life protection Act, *available at http://www.environmentallawsofindia.com/the-wildlife-protection-act.html (*last visited on June 23, 2017).
[153] Wildlife Protection Act, 1972, *available at www.wealthywaste.com (*last visited on June 23, 2017*)*

vital role in protecting the plants which has medicinal properties and which is used by the people for treating various diseases.

3.2.3. "GEOGRAPHICAL INDICATIONS OF GOODS (REGISTRATION AND PROTECTION), ACT,"[154] 1999

"Geographical Indication of Goods Act, 2003 is a "sui generis legislation enacted by union government of India, with the aim to protect the geographical indications of the country"[155]. "Under this act a product is defined by a geographical area where it is traditionally found. [156] "The first GI of India was given to Darjeeling tea, in 2004-05, since then 193 goods had been added to the list".[157]

3.2.4. PLANT VARIETIES PROTECTION AND FARMER'S RIGHTS ACT, 2001 (PPVFR ACT)

"Though India has adopted legislations that provide IPR protection but regarding the protection measure in agriculture the important factor that is taken into account is the concept of common heritage, or the principle of free exchange based on the view that the major food plants of the world are not owned by anyone and are a part of our human heritage".[158] "India established IPR laws to protect the rights of innovators, but attempted to balance this with the need for access to resources at reasonable prices"[159]. "The prohibition on the patentability of life forms and specifically methods of agriculture or

[154] Supra note 17.
[155] *Ibid*
[156] *Ibid*
[157] *ibid*
[158] IPR & Farmer's Rights in India, *available at https://www.linkedin.com/pulse/ipr-farmers-rights-india-bharat-kumar-singh* (last visited on June 13,2017)
[159] *Ibid*

horticulture was one of the hallmarks of the Patent Act 1970 with regard to food security"[160] "India's seed policy until the 1980s restricted the role of private sector in agriculture from old times public sectors had taken the in charge" [161] "Farmers were free to use, share and exchange seeds and since breeders could not acquire PBRs, there was no system of benefit sharing or compensation"[162]. Commercialization of agriculture, increasing use of high yielding varieties and hybrid seeds leading to decline in the use of traditional crop varieties and the subsequent entry of multinational seed companies required a review of agricultural policies to protect the rich base of plant varieties that India had. "PPVFR ACT was adopted to deal with the issue of farmers' rights within the FAO"[163]. "This was used by the NGOs for making the cause for protecting traditional knowledge of agriculture".[164]The PPVFR Act, 2001, the first legislation of its kind in the world that simultaneously recognizes and rewards the contribution of breeders and farmers to the development of new crop varieties, was enacted in the back drop of these various international and national events. It features a combination of provisions from UPOV 1978 and UPOV 1991 versions[165].The provisions in TRIPS which does not provide for protection of TK or farmers' rights to share of benefits from the commercialization of their crop varieties, provides for protection of plant varieties through grant of patent or effective *sui generis* IPR. The Government of India, therefore states that one of the reasons for its introduction as the need to protect the IPR associated with the development of plant varieties in fulfillment of an agreement signed by India

[160] Supra note 159.
[161]Anitha Ramanna, *India's Plant Variety and Farmers' Rights Legislation: Potential Impact on Stakeholder Access to Genetic Resources*,7 (2003)
[162] *Ibid*
[163] *Ibid*
[164] *Ibid*
[165]Sudhir Kochhar, *System Perspective for IPR protection in Plant Kingdom, 348,* (Vol. 9,2004).

under the WTO.[166] The implementation of this Act is vested with two national apex bodies, one administrative and other jurisprudential. The administrative apex body is the Protection of Plant Varieties and Farmers' Rights Authority. The judicial apex body is the Plant Varieties Protection Appellate (hereafter referred to as PVPA) Tribunal. However, the Rules of the Act do not anticipate establishment of the PVPA Tribunal. Rights accorded to farmers under the Act includes the right to seed, rights to register varieties, rights to reward and recognition, right to benefit sharing, right to information and compensation in case of crop failure, right to compensation for undisclosed use of traditional varieties, right to adequate availability of registered material, right to free services and protection from legal infringement in case of lack of awareness.

3.2.5. TRADITIONAL KNOWLEDGE DIGITAL LIBRARY (2001)

"India's TKDL, a collaborative project between the Council of Scientific and Industrial Research (CSIR), India's largest state-owned research body, and the Department of AYUSH,"[167] is a homegrown effort to ensure patent offices around the world do not grant patents for applications founded on India's wealth of TK that has existed for millennia"[168]. "The idea to establish a TKDL came to the fore amid India's efforts to revoke the patent granted by the United States Patent and Trademark Office (USPTO)"[169] on "the wound healing properties of *turmeric*, and the patent granted by the European

[166] S Bala Ravi, "*Effectiveness of Indian Sui Generis Law on Plant Variety Protection and its Potential to Attract Private Investment in Crop Improvement"* Vol. 9,533-548 (2004).
[167] TKDL to Protect Traditional Knowledge of Indian Medicinal System*, available at www.pib.ic.in/newsite/ProntRelease.aspx?relid=148831 (*last visited on June 14, 2017)
[168] Traditional Knowledge: As Intellectual Property, It's Protection and Roles in Sustainable Future, *available at https://www.rhimrj.com/admin/upload/MAY15020510.pdf* (last visited on November 12,2017).
[169] Supra note 44.

Patent Office (EPO) on the antifungal properties of *neem*"[170]. These endeavors, while successful, proved extremely costly and time-consuming. "Around this time the TKDL was established in 2001 .TKDL expert group estimated that, annually, some 2,000 patents relating to Indian medicinal systems were being erroneously granted by patent offices around the world."[171] For a patent to be granted an applicant must satisfy certain criteria as defined by national patent law, in particular, an applicant must prove that a claimed invention is novel and not previously known. Why then had patents been granted for so many applications relating to Indian medicinal systems? When patent examiners assessed these applications for patentability, the claimed inventions did not feature in the prior art searches carried out. They were, therefore, deemed patentable. At that time, however, much of India's traditional medicinal knowledge only existed in Sanskrit, Hindi, Arabic, Urdu and Tamil.

These languages were neither accessible to nor understood by patent examiners working in the major patent offices to which the applications had been submitted. The fact that so many patents had been wrongfully granted in the U.S. and Europe caused a great deal of national distress. The people of India felt that knowledge belonging to India was wrongfully being taken away from them. On top of this, these "wrong" patents conferred exclusive rights to exploit the technology in the country in which patent protection was granted. This posed a very real economic threat to Indian producers and to their freedom to operate in foreign markets. The TKDL has overcome these language barriers and is bridging the gaps in TK information in major patent offices. Using information technology tools and a novel Traditional Knowledge Resource Classification System

[170] Supra note 4.
[171] *Ibid.*

(hereafter referred to as TKRC), the TKDL has converted and structured ancient texts into 34 million A4-sized pages and translated them into English, French, German, Japanese and Spanish the major languages of international commerce. Today, India is capable of protecting some 0.226 million medicinal formulations and at zero direct cost. Access to the database helps patent examiners root out at an early stage those applications that clearly do not satisfy the novelty requirement. Without a database such as the TKDL, the process of revoking a patent can be a costly and time consuming affair. It takes, on average, five to seven years and costs between 0.2-0.6 million US dollars to oppose a patent granted by a patent office. Multiply this by India's 0.226 million medicinal formulations and it is clear that the cost of protection, without a TKDL, would be prohibitive in the country in which patent protection was granted. This posed a very real economic threat to Indian producers and to their freedom to operate in foreign markets.[172]

3.2.6. THE BIOLOGICAL DIVERSITY ACT 2002 AND RULES 2004

The Biological Diversity Act (BDA) 2002 was adopted following India's ratification of CBD. The CBD states that a member country should allow access to its genetic resources to other parties on mutually agreed terms, but that access requires the Prior Informed Consent of the country providing the resources. It also provides for an equitable sharing of benefits arising from these resources or TK about them. But countries must pass domestic legislation to bring these principles into their own laws. India's Parliament passed the Biological Diversity Act in February 2003 to address India's obligations under

[172] Traditional Knowledge Digital Library, *available at https://www.google.co.in/amp/s/www.gktoday.in/tkdl/amp* (last visited on June 15, 2017)

CBD".[173] Since the issue of protection of TK and Access and Benefit Sharing is new and still evolving and no other country had enacted a similar legislation, the enactment of the legislation had been a challenge. With providers and users of the resources often having opposing interests, the conflicting interests had to be reconciled. While on the on hand the Act had to regulate access to these resources by commercial interests of private enterprises, on the other, it had to ensure free access to biological resources for India's R&D both in agriculture and plant resources, and academic institutions. Added to this is the fact that India has a rich system of indigenous medicine both codified and non-codified, with almost 4 lakh registered practitioners apart from the local village and tribal medicine men. The number of stakeholders has therefore been large. While the Act mandates the scope of the CBD, the most important measures adopted by the Act focus mostly on access to biological resources and related issues. This is partly a response to the concerns over biopiracy in the second part of 1990s and partly in response to other developments such as the adoption of the TRIPS Agreement. The relatively narrow remit of the measures adopted can also be explained by the fact that there was no need to adopt a broad Act in a context where there were already a number of sectoral environmental laws India has at least 30 different legislations on biodiversity apart from the Biological Diversity Act. The positive aspect of this legislation is that it does not over rule other existing legislations. The difference between the Biological Diversity Act and PPVFR Act is that while Biological Diversity Act applies to plants, animals and micro-organisms PPVFR applies plants of economic value to human beings. Section 6(3) of Biodiversity Act states that applicants under the PPVFR Act 2001 are exempted from getting approval

[173] Biological Diversity Act, 2002

from the National Biodiversity Act. However, PPVFR Authority must endorse a copy of registration certificate to the NBA.

3.2.7. SIKKIM STATE BIOLOGICAL DIVERSITY RULES, 2006

Sikkim State Biological Diversity Rules was enacted in exercise of powers conferred by section 63 of the Biological Diversity Act, 2002. These Rules prescribe functions necessary to carry out provisions of Biological Diversity Act.[174] "Sikkim Biodiversity Board is a statutory body formed under Sec 22 of Biological Diversity Act 2002". "The Sikkim Biodiversity Board is under Forest, Environment & Wildlife Management Department".[175]

3.2.8. THE SCHEDULE TRIBES AND OTHER TRADITIONAL FOREST DWELLERS (RECOGINITION OF FORESTS RIGHTS) ACT, 2006

The Schedule Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006 was enacted to address the adverse living conditions of many tribal families living in forests. It identify and vests the rights and occupation of forest land in forest dwelling Schedule Tribes and traditional forest dwellers, "who have been residing in such forests for generations, but whose rights could not be recorded"[176]. This Act grants several other rights that is to ensure their control over forest resources which, inter alia, include right of ownership, access to collect, use and dispose of minor forest produce, community rights, right to protect, regenerate or con serve "or manage any

[174]Sikkim State Biological Diversity Rules, 2006, *available at https://www.ecolex.org/details/legislation/sikkim-state-biological-diversity-rules-2006.com* (last visited on June 24, 2017)
[175] Sikkim Biodiversity Board, *available at http://www.sbbsikkim.nic.in/* (last visited on June 12, 2017)
[176] *Ibid*

community forest resources which they have been traditionally protecting and conserving for sustainable use". [177]

Though there are number of protection measures but after analyzing the various protection measures at international and national level TK has not been defined nor is there any specific legislation that provides protection to it and the holders. Till date there is no protection for TK it is only regarded as a part of the biological diversity of a particular place and so only a little aspect is in light but TK as a whole is neglected which leads to biopiracy.

[177] Supra note 170.

CHAPTER 4

CASES AND DISPUTES OF BIOPIRACY IN INDIA

There are quite number of cases of biopiracy on TK especially from under developing biodiversity-rich countries. Developing countries like India, Brazil, and Malaysia, have faced several cases of biopiracy and due to this lost the rights to use or sell certain resources. Many corporations obtain patent "over biological materials without crediting the source of their knowledge or sharing the benefits"[178] that arise after selling such resources.[179] Most famous cases include patents obtained in other countries on haldi (turmeric), karela (bitter gourd), neem, basmati rice, medicines like jeevani etc. Granting of patent on such resources and failing to share the benefits of such traditional knowledge leads to biopiracy, though most of the patents were successfully contested and revoked, but to challenge such cases is very expensive and if there is no proper documentation patents can be granted easily. "Biopiracy is both legally and morally wrong. By allowing indigenous innovations to be treated as "inventions" of the patent "owner", biopiracy patents amount to the outright theft of a country's scientific, intellectual, and creative achievements and must be challenged."[180] All these disputes have raised the thorniest problems in patent law and rights to traditional knowledge. In the following pages some cases of biopiracy on the resources of India which constitute a part of traditional knowledge of the country are discussed.

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[178] Dr. Vishwas Kumar Chouhan,"*Protection of Traditional Knowledge in India by Patent: Legal Aspect*," IOSR Journal of Humanities and Social Science, Vol 3, Issue 1, 35-42 (2012).
[179] S.K, Tripathi, "*Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore: International, Regional and National Perspectives, Trends and Strategies,*" Vol.8, No.6, 468-77(2003).
[180] Biopiracy: Watch out, Monsanto's Patenting the chapatti!, *available at http://www.laleva.org/org/eng/2004/04/bio-piracy* (last visited on November 12, 2017).S

4.1 INDIAN CASES

4.1.1. Neem case

The botanical name of the neem tree is Azadirachta indica. The word has its root in Persian language, Azad-Darakth. Indians term the tree as azaddarakht-i-Hindil, the literal meaning is 'the free tree of India'. The neem tree is indigenous to the Indian subcontinent and can live upto two centuries. The tree has a history that has been mentioned in Indian texts written over 2000 years ago and used for agriculture applications as an insect and pest repellent and other veterinary medicine, toiletries and cosmetics purposes. Every part of this tree, from its root to bark, leaves and seed, has been used for medicinal purposes. It has also been used to cure illnesses. Neem oil itself is used for lighting lamps. It is also used as a religious item and is part of cultural and literature of the region. India's knowledge of its myriad uses has been known to the world community. Neem cannot be a subject matter of a patent because it has been indigenous to the region of South Asia and a part of its bio-knowledge and hence does not satisfy the criteria of novelty which is a necessary prerequisite for the grant of a patent. On the other hand, in the United States, neem seeds and their potent insecticidal extract, azadirachtin, have been the subject of continuing biotech research and grant of patents. An application was filed by multinational agribusiness corporation W.R. Grace of New York and the United States of with the European Patent Office (hereafter referred to as EPO) , which included a method for controlling fungi on plants with the help of a hydrophobic extracted neem oil in December 12, 1990. Thereafter, a series of patents for products derived from the neem tree have been filed with the U.S patent office and EPO for various claims including fungicidal effects, methods of extraction, and storage stable formulations of one of the

active ingredients, contraceptives, medical uses and insecticides. Overall, there were 90 patents on products from the neem tree. (Examples are patents Nos: 5,298,251; 5,356,628; 5,372,817; 5,405,612 and 5,409,708.) Patent applications were also filed by transnational pharmaceutical corporations such as Rohm and Haas. None of these claims involved genetically engineered products. Nonetheless, more than 90 patents have been granted worldwide in respect of several claims. For example, an U.S company, AgriDyne has patented two claims for bioprocessing of neem for bio insecticidal products. The first patent was for a refining process that removed fungal contaminants found in extracts from the neem seed which is used in the manufacture of technical-grade azadirachtin, and in the production of AgriDyne's neem based bio insecticides. The second patent was for a method of producing stable insecticide formulations containing high concentrations of azadirachtin. W.R. Grace had patents for neem based bio pesticides, including Neemix for use on food crops. For opposing these patents the three plaintiffs: Magda Aelvoet[181],Vandana Shiva,[182] and Linda Bullard filed an objection.[183] They claimed that fungicidal characteristics of hydrophobic extracts of neem seeds was known and used for centuries on a broad scale in India, both in Ayurvedic medicine and in traditional Indian agricultural practice to protect crops from being destroyed by fungal infections.[184] Since this traditional Indian knowledge was in fact present in Indian culture from ancient times, they asserted that the patent in question lacked two basic statutory requirements for the

[181] MEP, then President of the Green Group in the European Parliament, Brussels.
[182] She opposed the patents on behalf of the Research Foundation for Science, Technology and Natural Resource Policy, New Delhi, India.
[183] She represented the International Federation of Organic Agriculture Movements (IFOAM) based in Germany.
[184] Linda Bullard, "*Freeing the Free Tree: A Briefing Paper on the First Legal Opposition to a Biopiracy Patent: The Neem Case*," (2008).

grant of a European patent, viz., novelty[185] and inventive step.[186] It was also argued that the patent was contrary to morality[187] because the patentees claimed monopoly property rights on a method which forms part of the Indian traditional knowledge. The other grounds of challenge for the revocation of the patent included insufficient disclosure[188] and lack of clarity.[189] The patent was also challenged under Article 53 (b) of the EPC since it constituted a de facto monopoly on a single plant variety. There was a huge protest against this patent EPO submitted packages of signatures of lakhs of Indian citizens who demanded the revocation of patents on the neem. Interestingly, the patentee argued that the traditional Indian knowledge of neem tree properties was never published in any academic journal and such knowledge did not amount to prior art of that state[190]. However, after examination, the opposition panel found that the product had prior public use so the patentee's claim of novelty had been destroyed. The opposition division agreed with the opponents that no patents should be granted for anything which was known previously, for example as part of common TK since it is a question of novelty or prior public use. The Technical Board of Appeals also examined the patent with regard to novelty, disclosure and inventive step. In accepting the challenge and revoking the patent, the four-member panel of the EPO had agreed that the neem patents amounted to bio-piracy and that the process had been used in India from time immemorial so the patent was revoked.. Thus, on March 8, 2005 a legal history was made concluding a ten-year battle in the world's first legal challenge to a biopiracy patent, when the Technical Board

[185] The European Patent Convention, Article 54.
[186] The European Patent Convention, Article 56.
[187]The European Patent Convention, Article 53 (a)
[188] The European Patent Convention, Article 83.
[189] The European Patent Convention, Article 84.
[190] Intellectual Property Rights, *available at https:/www.894a018f-9e21-4256-835e-3eba9576fa96.doc* (last visited on November 20,2017)

of Appeals of the EPO revoked in its entirety the patent on a fungicide made from seeds of neem tree.

4.1.16 Turmeric case

Turmeric is a tropical herb mostly grown in East India. It has variety of uses including cooking, cosmetic products and medical purposes and has been used for thousands of years in India. In the mid-1990s, turmeric became the subject of a patent dispute when a U.S. patent on turmeric (No: 5,401,504) was granted to "the University of Mississippi Medical Center in 1995, specifically for the 'use of turmeric in wound healing"[191]. This patent also granted the patent holder the exclusive right to sell and distribute turmeric.[192] Concerns grew in India, where turmeric has been used medicinally for thousands of years, about the economic and social impact of this patent. Subsequently, India's Council of Scientific and Industrial Research filed a complaint by challenging the novelty of the University's invention. Then, the U.S. patent office investigated the validity of this patent.[193] Though the invention was non-novel since the process has in fact been traditionally practiced in India for many years and as such it was a common knowledge in public domain, the US patent rules did not recognize foreign undocumented knowledge as prior art if it was not known in the United States. It is only when the Indian government provided written proof including journal of the Indian medical association that was published in 1953 and an ancient Sanskrit text that documented turmeric's extensive and varied use throughout India's history, the patent on the anti-inflammatory applications of turmeric was revoked in 1997 on the ground of lack of novelty.

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[191] Supra note 47.

[192] Anuradha, R.V, Biopiracy and Traditional Knowledge, *The Hindu*, 2001.

[193] Biswajit Dhar and Anuradha, R.V, "*Access, Benefit Sharing and Intellectual property Rights," The Journal of World Intellectual Property*, Vol. 7, No. 5, 603-05 (2004).

4.1.17 Basmati rice case

Rice is an important part of life in the Southeast Asia. The farmers of these countries cultivate rice in a huge amount. For centuries, it has been the foundation of the regions food and culture. The farming communities throughout the region, over the years, have developed, nurtured, and conserved over thousand distinct varieties of rice. Among these varieties, basmati rice is known as the queen of fragrance. Basmati is aromatic long-grain rice which originated in Punjab. For many generations, Punjabi farmers in India and Pakistan nurtured the fragrant seeds while improving the yield. It has many characteristics from nut-like flavor to aroma that can be attributed to the peculiar geology where it grows the deep and fertile soils as well as the exceptional climate.

Basmati was thus viewed as a cultural and biological heritage. "India cultivates 650,000 tones of Basmati rice annually. About 10-15 per cent of the total land area under rice cultivation in India"[194]. "Basmati rice has been one of the fastest growing export items from India. Indian farmers exported $250 million Basmati every year"[195]. "Indian Basmati is imported especially by the Middle East, Europe and USA. Indian Basmati is considered as most expensive rice that is imported by the EU compared to Pakistani Basmati and Thai fragrant rice".[196]On September 2, 1997, an American company RiceTec Inc. was granted a patent (No: 5663484) on Basmati rice lines and grains by the USPTO. It related to the crossbred rice lines and grains developed by the U.S. Company. "RiceTec claimed a patent, from the basmati had been derived from Indian Basmati

[194] Trade Related Intellectual Property Rights (TRIPs) and Farmers' Rights, *available at http://www.publications.parliament.uk/pa/cm199900/cmselect/cmenvaud/45/45ap08.htm>* (last visited on June 12,2017)
[195] *Ibid.*
[196] *Ibid*

crossed with semi-dwarf varieties, including indicia varieties"[197]. "Rice Tec was awarded patent rights on Basmati rice and grains and traded the same in its brand names such as Kasmati, Texmati and Jasmati."[198] In all, the company made 20 claims in the patent application, including a method for the development of novel rice lines. The claims 15 to 17, were clearly threatening India's interest which defined rice grains without any limits or territory or photo period selfishness. These claims were generally worded so that it could comprise 90 percent of rice germplasm and even traditional rice lines like Bas 370, Taraori Basmati, Karnal local and other varieties. On India's protest RiceTec withdrew these claims. RiceTec had got patent mainly for three categories growing rice plants with certain characteristics identical to Basmati, the grain produced by such plants, and the method of selecting the rice plant based on a starch index (SI) test devised by RiceTec Inc. Out of these three categories, India challenged only the claim on 'grain quality' and left the claims on 'variety of the rice' and 'its method of production' unchallenged. The government of India has challenged the patent through Agricultural and Processed Food Exports Development Authority (APEDA). The patent was challenged on technical grounds of novelty, usefulness and non-obviousness. An application for patent re-examination was filed before the U.S. Patent and Trademark Office (USPTO). Subsequently, RiceTec withdrew all the claims except those which associated to the definite rice lines developed by it and not to any varieties or lines grown in India. During the course of the appeal filed by India in the U.S., Ricetec dropped 15 out of the 20 claims that it had made in the original patent application.

[197] Supra note 195.
[198] *Ibid*

Ricetec has been finally granted varietal patents for three strains of superfine rice developed by the company, but it could not obtain patent for the generic and pseudo generic strains of basmati. In the ruling, the USPTO said that RiceTec's grain is equal or superior to good quality Basmati. This would help the company to label its strains as superior Basmati rice. Even after cancelling the patent indirectly rights were given to the company. The global population treated this as a obvious case of biopiracy that threatens the genetic material, biological resources and indigenous innovation of farmers around the world.[199] "Research Foundation for Science and Technology, the Basmati patent is a clear case of biopiracy and represents a theft in three ways i.e. stealing of communal intellectual biodiversity legacy of Indian farmers who have evolved and bred Basmati varieties, theft from Indian traders and exporters whose markets are being stolen by the theft of Indian basmati rice, and "theft of the name Basmati which describes the aromatic characteristics of the rice"[200].

4.1.18 Narcissus tazetta case

Nargis Narcissustazetta (hereafter referred to as N tazetta) is a famous plant having various medicinal properties as documented in ancient Unani classical literature.[201] It is used as solvent (mohallil), absorbent absorbefacient (jaazib) and jaali (detergent), and also for the treatment of 'balkhora' (Alopecia areate) as mentioned in Khazainul Adviyah by Ghani. Moreover, it is useful for the treatment of 'Kalaf' (freckles), and bahaq

[199]Basmati- Pride Of India- A Case Comment, *available at https://www.lawctopus.com/academike/basmati-pride-india-case-comment-1998-case-493* (last visited on June 14, 2017)
[200] Supra note 195.
[201]Abu Ali IbnSina, Al-Qaanoon-fil-Tibb, *"Institute of History of Medicine and Medical Research (IHMMR)",* New Delhi, vol. II, 398, 1987.

(Ptyiasis) as mentioned in Al-Qaanoon-fil-Tibb (AD 981–1037). This plant has a numerous medicinal uses. A patent application (patent no. 04005448.8) with publication number EP1718142, published on 8 September 2004 as follows 'Agents for sequestering serum ageing factors and uses therefore'[202]. The discoverer of this claim was Kern Dale from US and the applicant was Nu Skin International Inc of US. The patent claims that the Narcissus product can be used for preventing harm to the skin, treating the damaged skin, preventing a difficulty of the primary disorder and preventing the secondary disorders, when in all the above cases the complication results from oxidative damage resulting from the generation of reactive oxygen species by arNOX. The prior arts of Unani classical literature against the novelty and inventiveness of the claims of the patent application in which N tazetta had been used for the prevention and treatment of damaged skin. One of them taken from Al-Qaanoon-fil-Tibb Canon of Medicine referred to a description of N. tazetta as a single ingredient used in the treatment of alopecia through local application. Another art taken from Al-Jaame'-li-Mufradaat-al-Adviawal-Aghzia referred to a formulation containing N.tazetta as a single ingredient used in the treatment of alopecia through local application. The alleged invention claimed the use of N. tazetta for the prevention and treatment of damaged skin resulting from conditions like acne vulgaris, atopic dermatitis, alopecia, vitiligo, pruritus, eczema, etc. However, N. tazetta had been used singly and in mixture with other constituents for treating alopecia, pruritus and vitiligo through local application as is seen in the prior art. There is a document which acts as an evidence to reject the claim of the patent.

[202]Mohd Najmul Ghani Khan, Khazaain-al Advia (urdu translation), Idara Kitaabul Shifa, New Delhi, 1311, 1926 AD.

4.1.19 Bt Brinjal Case

Brinjal, which is the Indian name of eggplant, has been cultivated in India by millions of farmers, who have developed 2,500 varieties. This plant is popular in Indian recipes and also used as a religious offering in some areas of India.

A complaint lodged by the Environment Support Group (hereafter referred to as ESG), a nongovernmental organization based in Bangalore, before the Karnataka Biodiversity Board on 15 February 2010.[203] The Group had gathered and published many official documents regarding this case on its website.[204] After investigating the file, the Karnataka Biodiversity Board informed National Biodiversity Authority (hereafter referred to as NBA) on 28 May 2011 that, "six local varieties for development of Bt brinjal were accessed in the state by the two companies without prior approval from State Biodiversity Board/ National Biodiversity Authority''[205]and called for legal action. The Indian farmers' growing protests against Bt brinjal had encouraged the Minister of Environment to announce on February 2010, just before the ESG's complaint, a moratorium on Bt brinjal until there was a public consensus on health and safety issues. The NBA decision charges three entities with alleged violation of the Biological Diversity Act, ''for accessing and using the local brinjal varieties for development of Bt brinjal without prior approval of the competent authorities."[206]The authority decided to proceed legally against Mahyco and Monsanto, and all other concerned to take the issue to its logical

[203]Monsanto and Its Indian Collaborators for Biopiracy, *available at www.esgindia.org/campaigns/brinjal/ press/national-biodiversity-authority-prosecut*.html (last visited on July 12, 2017)

[204]ESG web site: www.esgindia.org/campaigns/brinjal/press/ national-biodiversity-authority-prosecut.html

[205]Letter from Karnataka Biodiversity Board to The Secretary, National Biodiversity Authority, dated 28 May 2011; *available at www.esgindia.org/sites/default/files/campaigns/brinjal/press/ b-bt-brinjal-kbb-nba-biopiracy-submission.pdf* (last visited on 1:00p.m. August 12, 2017)

[206]*P*BR Formats (NBA) - National Biodiversity Authority*, Available at www.nbaindia.org/docs/20th_Proceedings_10_ 08_2011.pdf at 7 (*last visited on July 13, 2017).

conclusion''[207]for violation of the Biological Diversity Act, 2002.[208] At its meeting on 28 February 2012, the NBA, by majority vote, reaffirmed this decision.[209]The Bt brinjal controversy prompted at least one brinjal grower community to protect its traditional brinjal variety. An application by Mattu Gulla Growers Association, facilitated by the Department of Horticulture, Karnataka, to protect their unique brinjal variety called *Udupi Mattu Gullazz* resulted in it getting Geographic Indication (GI) status in May 2011, denoting its origin in Mattu Village, Udupi, and its unique properties.[210] GI status renders a formal legal identity to a variety and if the variety is modified, those who made the modification will be prevented by virtue of the GI from denying the source of origin and the grower community will be eligible for benefit sharing.

4.1.20 Asian chick pea case

Chick pea (*Cicerarietinum*), one of the most primitive cultivated vegetables, is the most significant cool season food legume crop grown mostly by small farmers in the semi-arid tropics of West Asia and North Africa. Farmers from Indian subcontinent grew them massively all year round. India is the world leader in chickpea production followed by Pakistan and Turkey. Chickpeas have high protein, dietary fiber, and zinc and thus a healthy source of carbohydrates for persons with insulin sensitivity or diabetes. Two Australian government agencies collected samples of Asian chick pea from the

[207]Dinesh C. Sharma, Heat on Monsanto for brinjal piracy*, Mail Today,* 12 August 2011.
[208]Priscilla Jebaraj, NBA for action against BT brinjal biopiracy, *The Hindu*, 10 August 2011.
[209]Verma, S. ,Btbrinjal row: National Biodiversity Authority decides to prosecute Monsanto*, India Today*. New Delhi. India*. Available at http://indiatoday.intoday.in/story/bt-brinjal-row-monsantoto- pay-for-biodiversity-violation/1/184824.html* (last visited on July 20, 2017)
[210]Naik, M.G. UdupiGulla gets patent protection *Deccan Herald. Available at http://www.deccanherald.com/content/89223/udupigulla- gets-patent-protection.html (last visited on July 20, 2017).*

International Crops Research Institute for the Semi-Arid Tropics (hereafter known as ICRISAT). ICRISAT is a globally funded public research center based in Hyderabad. In April 1997, the agencies representing Australian seed industry applied for patents and plant breeder's rights (PBR) on two strains of these chick pea varieties. Neither of these variety were novel to the farmers. Indeed, both the claimed varieties originated in farmer's fields in India and Iran. On protest, the Australian agencies withdrew their patent applications in January 1998.

4.1.21 Ginger

A patent specification titled "pharmaceutical composition for the treatment of excess mucous production was filed at British Patent Office having a patent priority date of March 16, 2006 by the inventor Nicholas John Larkins. The British patent application discloses a composition comprising ginkgpbiloba or extract or component there of apocynin and a gingerol. The composition can be used to treat diseases such as cystic fibrosis and chronic obstructive pulmonary disease".

The patent application found that compositions according to the invention may have a remarkable effect in reducing excessive mucous production. Moreover, the use of gingerol in combination with ginkgo biloba (or extract or component thereof) and apocynin provided a substantial clinical improvement Zingiber Officinale is the scientific name for ginger and commonly known as adrak in India. Ginger has been used as medicinal remedy for cough and cold since ages in India. Moreover, the medicinal properties of ginger have been the traditional knowledge of India. Consequently, the Department of AYUSH and Council of Scientific and Industrial Research (CSIR)

intervened and provided evidence from age-old Ayurveda and Unani books, dating back to the 18th century that talked about ginger to treat cough and other diseases.

Patent prior art knowledge was retrieved from the Traditional knowledge Digital Library (TKDL) database of India and submitted at the United Kingdom patent office. Subsequently, the patent examiner took into consideration of the prior art TK of India and rejected the patent application for the ginger based pharmaceutical composition for the treatment of excess mucous production.

4.1.22 Jeevani

The case of Jeevani drug is a case of benefit sharing in India. The traditional knowledge that was practiced in India was used in the context of indigenous people and the people were given share of profits, but this practice did not prove beneficial to the indigenous people. [211]

Jeevani is a restorative, immune-enhancing, anti-stress and anti-fatigue agent, based on the herbal medicinal plant arogyapeacha, used by the Kani tribal in their traditional medicine. "While the Kani tribe members only used the fruit of the plant Jeevani was the product from leaves and was never used by the Kani tribe members."[212]

Patent applications were filed by Tropical Botanical Gardens Research Institute (hereafter referred to as TBGRI) "for the purpose of making the new innovations. There was no patent on the product at that time, India did not have a product patent regime it was only

[211] Arogyapacha: A "Green" Approach to Pharmaceutical Innovation, *available at https://spicyip.com/2008/01/arogyapacha-green-approach-to.html* (last visited on July 14, 2017)

[212] The Realities of Traditional Knowledge and Patents in India, *available at https://www.ip-watch.org/2010/09/27/the-realities-of-traditional-knowledge-and-patents/ (*last visited on July 15, 2017)

after seven year process patent was accessible."[213] "Five patent applications originated from the study. Five process patents were filed since 1994. There were three patent applications on Arogyappacha, one was for treating diabetes, the second a sport medicine, and third for treating cancer."[214]

The Tropical Botanical Gardens Research Institute "licensed the process for manufacturing and marketing the drug to Arya Vaidya Pharmacy, a private company, for a period of 7 years (the term of the pharmaceutical patent at that time) for a consideration of an upfront license fee of Rs 1 million (USD $25,000) and a right to receive royalties from the sale of the drug at a rate of two percent ex factory price on the sales of the product. Jeevani was successfully sold in India as well as in other countries like the United States of America and Japan."[215] "At that time neither the Biological Diversity Act nor the Forests Rights Act had come into existence but the TBGRI voluntarily agreed to share 50 percent of the license fee and 50 percent of the royalty from the licensing agreement with the Kani tribals. A trust for keeping the money was set up with the help of officials of Kerela State Government; a fixed deposit was kept, and used the interest for activities benefiting the Kani community".[216] Subsequently, a majority of the Kani families became members of the trust" [217]. "The establishment of trust fund was to share the benefits that would arise from the commercialization of the traditional

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[213] Intellectual property, Innovation and Management in Emerging Economies, *available at https://docslide.net/documents/intellectual-property-innovation-and-management-in-emerging-economies* (last visited on December 13, 2017).
[214] Supra note 213.
[215] *Ibid*
[216] Realities of Traditional Knowledge And Patents in India ,*available at https://www.ip.watch.org/2010/09/27/the-realities-of-traditional-knowledge-and-patents-in-india* (last visited on December 23,2017)
[217] *Ibid.*

knowledge."[218]. "The Forest Department never interfered with the Kani's activities in collecting the plant but after the properties of the plant became well known traders started entering the forest in search of the plants and removed the plant in large quantities. Due to this the Forest Department had to stop all collection activities, thus curtailing and punishing even the traditional collection by the Kanis. Lot of attempts was made to cultivate the plant in nurseries outside the forest, but it was found that the nursery grown plants did not have the same properties as the forest variety. Financially, therefore, everyone lost out but the Kanis tribe members lost more than any other".[219]

4.1.23 Karela case

For thousands of years, the common Karela (bitter gourd) has been valued by the people of India for its incredible curative properties. Despite its bitter taste, Karela has always been considered as a vegetable with almost miraculous properties which range from curing diabetes to cleansing the blood of cancer patients. On May 4, 1999, however, the Karela along with Jamun, Brinjal and Gurmar became a patented herb when patent number 5,900,240 was granted to Cromak Research Inc. which was based in New Jersey. The scientists who own the patent were non-resident Indians Omkar S Tomer and Kripanath Borah, and their colleague Peter Glomski. The patent was granted on edible herbal compositions comprising mixtures of at least two Indian herbs selected from a group consisting of syzygiumcumini, popularly known as jamun, momordicacharantia (bitter gourd or karela), solanummelongena (brinjal or eggplant) and gymnemasylvestre

[218] Arogyapache: A 'Green' Approach to Pharmaceutical Innovation, *available at https:spicyip.com/2008/01/arogyapache-green-approach-pharmaceutical-innivation* (last visited on December 14,2017).
[219] Supra note 213.

(gurmar). As an example, Indian researchers have discovered that Karela alone had many curative properties which had hitherto gone unexplored. When the chemicals in Karela seeds were purified, it was discovered that they contained an inhibitor of HIV, the AIDS Virus. In addition, Indian scientists who were guided by ancient Indian texts also found that Karela juice was a useful therapeutic agent for treating tumours and purifying blood. The fruit and seeds were reported to exhibit anti-leukemia, antiviral and anti-ulcer properties. The Lectins and fatty oil in the Karela seeds exhibited antibacterial activity. The oil also showed significant insecticidal propensities. Given the incredible usefulness of the humble Karela alone, one's mind is boggled by the curative potential of thousands of Indian vegetables, herbs and fruits.

The scientists had been granted the patent for their claim that they had developed a novel herbal drug for treatment of diabetes, including insulin-dependent diabetes, using mixtures of powders of at least two out of the four plants. The patent outright ignores the fact that these plants have been in use in India for thousands of years as a treatment for diabetes. The medicinal properties of these and thousands of other medicinal plants are elaborately detailed in number of Hindu texts. The benefits of Karela are known to India and are revealed from the descriptions in the CarakaSamhita, SusrutaSamhita, Brhatsamhita to the detailed pharmaceutical instructions in Upavanavinoda, for centuries together. India's scholars have been at the fore front of botanical medicine. The ancient Ayurveda has been a guide to good health and even spiritual enlightenment for thousands of generations of Indians. This natural science has by no means lost its influence or importance to today's world. It is in fact more relevant than ever to the present and future

as modern technology enables us to explore the healing properties of the recommended plants even further[220]. But even having all such proof the patent rights were granted.

4.1.24 Ashwagandha case

"The European Patent Office rejected an application from the US-based Natreon on the medicinal properties of the plant Withaniasomnifera on March 25, 2010. Latin name for Ashwagandha, Natreon calimed that it had developed a novel method to treat or look at a number of stress-related conditions and submitted the application in 2006. The patent application for Ashwagandha had already failed in Europe but the United States Patent Office"[221] had "already granted Natreon a patent on a number of Withania based products. Natreon advertised that it used Ayurvedic medicine to offer unique, patented ingredients created after complete research. It claimed with broad portfolio of products and technologies, to provide unmet nutritional supplement, functional food, and pharmaceutical market needs."[222]

This was a case of bio-piracy because Ashwagandha was always regarded in India as miracle herb. Dr. V.K Gupta clearly proved that the medicine was already documented in India. Therefore there was no novelty in the application. Natreon withdrew the application of claiming patent over it. "More than 2,000 formulations based on India's traditional medicine systems have been awarded patents either in the United States or in the European Union. The use of brahmi for memory, ginger for obesity, citrus peel

[220] Bio-Piracy And The Need For Protection Of Traditional Knowledge In India: The Selected Case-Studies, *available at http://ilovehyderabad.com/columns/columns-will-india-lose-its-ayurvedic-heritage.html* (last visited on July 17, 2017)

[221] Pirates of Traditional Knowledge, *available at http://udayindia.in/2010/07/10/pirates-of-traditional-knowledge/ (*last visited on July 20, 2017)

[222] Supra note 222.

extract for skin diseases, and mustard for the stomach has already been used by various Corporations. But they are claiming patents over the Indian home remedies that are part of kitchen medicine cabinets and cuisines"[223] and it should be stopped. "With great effort and support of the public the government managed to get some patents revoked, such as on neem and turmeric, but it took many years and cost a lot"[224] This indicates the need for a separate mechanism or a sui-generis system of protection in India for food and medicines derived out of traditional knowledge.

4.1.25 Monsanto's wheat patent case

"In 2003 the European Patent Office granted a patent on Galahad 7 (Number EP 445929), a wheat variety which relied on a traditional variety from India called Nap Hal under the plant category"[225]. "Due to the special characteristic feature i.e.low levels of gluten, Nap Hal possessed low visco elasticity which could render the dough ideal for making chapatis and biscuits. In 1997 USA granted similar patents for low visco elasticity wheat blends as US patent number 5859315 and US patent number 5763741"[226].

When the issue for paying royalties for making biscuits and chapattis was discussed at the Parliament made everyone worry."[227]

"It was in 2004, that Vandana Shiva's Research Foundation for Science and Technology and Ecology filed a writ of mandamus was filed at the Supreme Court asking the court to

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[223] Supra note 213

[224] Supra note 222.

[225] Biopiracy in the context of Plunder of Wheat in India*, available at https://spicyip.com/2016/03/spicy-ip-fellowship-2016-17-biopiracy-in-the-context-of-plunder-of-wheat-in-india.htm*l (last visited on July 21, 2017)

[226] Supra note 226.

[227] Biopiracy in the context of Plunder of Wheat in India*, available at https://spicyip.com/2016/03/spicy-ip-fellowship-2016-17-biopiracy-in-the-context-of-plunder-of-wheat-in-india.htm*l (last visited on July 21, 2017)

direct the center to challenge the patenting of wheat before the EPO. The petitioner also highlighted the concern relating to patenting of misappropriated TK. The petitioner claimed that the patent specification involved an Indian wheat variety which was a result of indigenous research over thousands of years".[228]

"The government submitted that since Nap Hal itself had not covered by the European patent, Nap Hal would be available for Indian researchers and farmers. It maintained that Monsanto could not enforce the patent in India through the Patent Cooperation Treaty, 1970 as the same could not undermine the national legislation of convention countries"[229].

"While the Supreme Court issued notices to various government departments, a petition was filed at the EPO by a consortium involving Bharat Krishak Samaj, Navdanya and Green peace, Germany for revoking the patent"[230]. The EPO withdrew the patent, agreeing with the then patent holders, who had requested a withdrawal citing no commercial viability.

"The report by the Co-ordinate Group, set up under the chairmanship of Secretary, Department of Agricultural Research and Education recommended in 2007 that no action be pursued as the huge cost of litigation was unwarranted, given how, one of the two US patents had lapsed in 2007 due to non-payment of maintenance fee while the second one would expire in 2010 and a subsequent affidavit by Indian Council of Agricultural Research reiterated the same.

Noting that the patents in question had all been, either revoked or expired, the Supreme Court dismissed Research Foundation for Science Technology and Ecology & Anr. V

[228] Supra note 228.
[229] *Ibid.*
[230] *Ibid.*

Union of India, Writ Petition (Civil) NO. 64 OF 2004 in 2016. The Supreme Court lauded the efforts of the government in combating biopiracy but refused to direct setting up of a board to pursue litigation against patents based on traditional knowledge. In its written order, it requested the petitioner to make a representation to the Central government of its proposals."[231]

4.1.26 Monsanto's Biopiracy of Indian Melons case

"The US company Monsanto was awarded a European patent on conventionally bred melons (EP 1 962 578) in May 2011"[232]. But the original stem of the melons was from India and it had a natural resistance to certain plant viruses. "With the help of conventional breeding methods, this type of resistance was introduced to other melons and claimed patent over it. The actual plant disease, Cucurbit yellow stunting disorder virus (CYSDV), has been spreading through North America, Europe and North Africa for several years"[233]. And this Indian melon, could resist this virus, and had already been registered in international seed banks as PI 313970".[234] "But as the patent was granted so it could block access to all breeding material inheriting the resistance derived from the Indian melon. The patent could also put off future breeding efforts and the progress of new melon varieties. Not only this could the breeders and farmers of melons be denied use because of the patent. The patent was opposed by several organizations in 2012"[235].

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[231] Spicy IP Fellowship 2016-2017: Biopiracy in the context of Plunder of Wheat in India, *available at https://spicyip.com/2016/03/spicy-ip-fellowship* (last visited at December 17, 2017).
[232] *Ibid.*
[233] *Ibid*
[234] Seeds, Biodiversity and IPRS, *available at https://medium.com/@drvandanashiva/seeds-biodiversity-and-iprs-845187d00951* (last visited on July 24, 2017)
[235] Seeds, Freedom and Food Democracy, *available at https://www.navdanya.org/site/seed-freedom-and-food-democracy/* (last visited at December 15,2017).

4.1.27 Monsanto's Biopiracy of Climate Resilience

"Monsanto is a well known corporation that has claimed patent over many products and processes that are based upon the traditional knowledge of India it has even applied patent for Methods of Enhancing Stress Tolerance in plants and methods."[236] The title of the patent was later amended to 'A method of producing a transgenic plant, with increasing heat tolerance, salt tolerance or drought tolerance'. The particular qualities have been evolved by the Indian farmers over many generations by applying their understanding of breeding. But the claim was dismissed by Hon Justice Prabha Sridevi, Chair of the Intellectual Property Appellate Board of India, and Hon Shri DPS Parmar, technical member on 5th July, 2013.

More than 1500 patents on Climate Resilient crops have taken by corporations like Monsanto. Due to climate instability this resilient traits have become increasingly important. There are many innovations that the farmers have come up with for e.g. along coastal areas, farmers have evolved flood tolerant and salt tolerant varieties of rice such as"Bhundi","Kalambank","Lunabakada","Sankarchin","Nalidhulia","Ravana","Seulapun i","Dhosarakhuda" etc. Not only these crops such as millets have been evolved for drought tolerance, this provides food security in regions where water is scarce"[237].

"But without proper mechanism to protect the innovations that the farmers come up with would lead to patent on the same, so it is necessary that the legal systems recognize the rights of communities, their collective and cumulative innovation in breeding diversity.

[236] Supra note 226.
[237] Supra note 236.

The idea of IPRs was given a lot of support and encouragement but now its time to evolve categories of community intellectual rights (CIRs) related to biodiversity."[238]

4.1.28 ConAgra's Biopiracy claim on Atta case (Wheat flour)

"Atta, is a staple food and used in many things from cooking various eatables. Many culture programs various foods made out of atta hence it is well known by the people of India. But this food is under threat from various corporation especially corporation ConAgra. The corporation also filed a "novel" patent (patent no 6,098,905) claiming sole ownership over the process through which atta is made, and on August 8th, 2000 the corporation was granted patent for the same. The novel process that the corporation ConAgra is claiming has been used throughout South Asia by thousands of atta chakkis, which gives an evidence of prior art".[239] Before and even till today patents are claimed over the products and process that are based on the traditional knowledge of people and due to this biopiracy takes place. If such patents are not challenged, than the "exclusive properties that has been developed through indigenous breeding become the monopoly of MNC's"[240],and the people who have developed in turn would be bound to pay royalties ."

4.1.29 Phyllanthus niruri case

Phyllanthus niruri is one of the medicinal plants used widely all over India. It is used to treat various types of hepatitis and other liver disorders. It is used locally and is a part of the health care system; it is also part of folk medicine, traditional indigenous collective

[238] *Supra note 236.*
[239] *Ibid*

[240] Vandana Shiva, *"Monsanto's Biopiracy", available at https://www.countercurrents.org/en-shiva270404.htm* (last visited on August 20, 2017)

knowledge etc. The plant is called Bhudharti in Sanskrit, Ja amla in Hindi and Bhuin amla in Bengali. The entire plant – its leaves, shoots and roots is used for treating jaundice. Even though the uses of the plant for treatment of jaundice is known through ancient times and is a well recorded innovation in Indian system of medicine, patents are now being applied for this kind of knowledge as if it were a novel invention.

The Fox Chase Cancer Centre of Philadelphia, USA, applied to the European Patent Office for the use of Phyllanthus niruri in curing hepatitis. The patent claim was for manufacturing of medicament for the treatment of viral hepatitis B. The patent application refers to Dr. K.M.Nadkarni's Indian Material Medica which reports that formulations based on Phyllanthus niruri are used for treatment of jaundice in classification and folk traditions. Despite the fact of prior knowledge of its use as a cure for all forms of hepatitis, including hepatitis B, the Fox Chase cancer claim states that Phyllanthus niruri has not been proposed for the treatment of viral hepatitis.[241] Even when the use of the plant is known the researchers tend to claim rights over it. The above mentioned are some of the examples.

[241] Vandana Shiva, "*Protect and Plunder?" Understanding Intellectual Property Rights*, 49-52, Zed Books (2001).

CHAPTER 5

PROTECTION OF TRADITIONAL KNOWLEDGE FROM BIOPIRACY IN SIKKIM

This chapter deals with the protection measures for TK in Sikkim, its importance and the link between TK and the indigenous people. The data has been gathered by conducting interview method. Interviews of the officials of biodiversity boards, forest departments and the local people who have been practicing the traditional methods for healing, treating diseases were conducted (see Appendix 1). Unstructured[242] interview was conducted. So, even when certain questions were prepared beforehand different questions were put up while conducting the interview so that more information could be obtained. Most of the questions were based on how TK is protected, the various measures that are adopted by the Government to inform the local people about the importance of TK; the protection that is awarded to the traditional knowledge holders and the main cause of biopiracy in Sikkim? Interviewing the local people who have been practicing the traditional methods brings to light how traditional knowledge plays a vital role in the day to day life of people in Sikkim. Be it while cooking some type of dishes, or cultivating certain type of crops or preparing some medicines for different diseases, traditional knowledge are essential part of the culture, religion and literature of the people.

As discussed in the preceding chapters though a lot number of protection is highlighted in various Conventions, Declarations but there are very few measures that are adopted for protecting TK. Under TRIPs agreement though various forms of intellectual property

[242] Unstructured interviews are open ended instrument where interviewer has a list of topics that the respondent needs to talk about but are free to phrase questions as the interview proceeds.

rights are given protection, but there are only few provisions for protection of TK. Providing protection under the various intellectual property rights seems to be a difficult challenge in respect to TK. TK is that area, which has been disregarded even though when it has social and economic value and links the tradition of a certain place or people. Many debates, conventions have been conducted to highlight the issue for protection of TK but very little has been done. Moreover, people try to claim patent on the inventions which they carry out using the TK of the indigenous people. All around the globe the issue for protection of TK is identified though some countries has adopted measures for protection of the same. With the widespread concern for protection of TK form biopiracy, even India has laid down few provisions for protecting it. But, the issue of biopiracy has to be dealt more strictly. TK is now widely recognized as having played and as still playing crucial roles in economic, social and cultural life and development not only in traditional societies but also in modern societies.[243] India has recognized the importance of TK and there is a result of the increased awareness of the environmental crisis that is lead due to misappropriation of it and also recognizing the contribution of the local communities for protecting the same. Moreover there is an increased awareness of the role and critical importance of TK. As India is a developing country and most of the population in India are engaged in agriculture, so the knowledge of farmers and indigenous peoples on how to use and what type of resources to use, how to conserve these resources, is now being recognized as a precious resources that is important for the future development and even survival of humankind. This precious knowledge has been passed on from generation to generation and must be maintained properly. The important

[243] Martin Khor, I*ntellectual Property, Biodiversity and sustainable Developmen*t, Resolving the Difficult Issues, (Zed Books 2002).

concern for protection of TK is that the misappropriation of the products of their knowledge would not only violate their rights, but also adversely affect the conservation and use of the knowledge and of biodiversity. So, there is a need to acknowledge the importance of TK:

- To benefit the social and economic context traditional knowledge should be maintained properly,
- The rights of local communities to their resources and knowledge have to be recognized and respected.
- There must be a strict rule on controlling the misappropriation of these rights as it can erode the basic traditional knowledge which could adversely affect the prospects of sustainable development.

5.1 Importance of Traditional Knowledge in Sikkim

In Sikkim TK has played a crucial role to provide identity to the people and also helped them in economic, social and cultural development. TK not only provides a sense of brotherhood among the people but also help them for the development and their survival. People have come up with many methods for example to cultivate crops, to sow the seeds, to make medicines, to make handicrafts that represents a culture and this methods , techniques are the traditional knowledge of the people who have developed it and has been using it since old times. The misappropriation of their resources, their knowledge or the product of their knowledge would not only violate their rights, but also adversely affect the conservation and use of knowledge and of biodiversity as the IPRs obtained by corporations or institutions may hamper the communities rights to continue using the

resources which help them to do their traditional practices.[244] TK makes a valuable contribution to the two main aspects of sustainable development: the environment and the fulfillment of human needs.[245] TK has contributed to the general knowledge on sound environmental principles and management, such as in forest conservation, soil conservation, seed conservation and crop biodiversity. There are majority of population that still depends on TK and practices of food and medicines. The contributions of TK to the economy, especially to agriculture innovation and development and the drug industry are also large. Many pharmaceutical companies have used the TK identified by the indigenous people and also the ingredients for developing new medicines. Sikkim is known as a biodiversity hotspot with wide varieties of macro flora and fauna. The ethnic population living here relies on an intimate knowledge of the bio resources found locally for their survival. There are many areas which are very rich in bio resources that have high medicinal values and which constitute an essential part of TK. Most of the people still use the medicines that are derived from medicinal plants found in Sikkim. TK of ethnic groups which reflects the experience of many generations is closely associated with human development. Lack of systematic documentation in written form and reliance on oral tradition along with the recent development and modernization activities is leading to irretrievable loss of this ancient tradition. Due to this biopiracy is taking place. The issue of biopiracy is prevalent in Sikkim but they are mostly off the record.[246] Certain instance were there when the people were caught illegally taking away the bio resources from Sikkim. There are areas where the resources are concentrated in huge

[244] Martin Khor, I*ntellectual Property, Biodiversity and sustainable Developmen*t, Resolving the Difficult Issues,16 (Zed Books 2002).
[245] *Ibid*
[246] Information gathered while conducting interview with the Board member of Sikkim Biodiversity Board Mr. Bharat Pradhan on November 2, 2017 at 12:30 p.m.

quantity North Sikkim is one of the areas where number of TK is followed. The people who reside there have followed those traditions for ages and they are a part of their life. People residing there use the plants available to make medicines to treat themselves from diseases; they have the knowledge of various types of medicinal plants. After various trials and efforts the people have identified the medicinal qualities of plants. They have developed various techniques of fishing, agriculture which are a part of their TK and they have been following those from generations after generation. The other thing that North Sikkim is famous for is tourism activities hundred and thousand of tourist visits North Sikkim and no doubt there are many people who have the information about the rich traditional knowledge the people of that place holds. So, there were in stances where the researcher came as tourists to learn certain traditional knowledge. But with the biopiracy instance the people of North Sikkim do not share the knowledge that easily. But, this is not the case everywhere.[247] The people have come up with the knowledge and they use it in their day to day life. But with the advent of IPRs the situation has changed. The idea of IPRs which is product of developed countries has affected the developing countries the most. The developed countries have huge advancement in technology but lacks resources, whereas the developing countries have a wide variety of resources which makes them the target of the developed countries, the multinational corporation's etc. Though the developing countries have also come up with laws to safe guard the bio resources, there are still many steps that need to be taken to comply with it. Talking about Sikkim, there are as mentioned many issues regarding to bio piracy but they are mostly of the record, the theft or so called piracy is not recorded may be due to lack of evidence or lack of

[247] Information gathered while conducting interview with Mrs. Usha Lachungpa, former Principal Research Officer, (FEWMD) of Sikkim Biodiversity Board on June 7, 2017 at 12:30 p.m.

proper legislations. There are several ways in which biopiracy is taking place but in Sikkim one of the important agents is tourism. In Sikkim there is huge traditional knowledge that the people follow. They have been using such knowledge since ages and are part of their cultures and tradition. The indigenous people in Sikkim use the knowledge to treat some diseases, and also use it to make different types of products in traditional ways. Sikkim has a rich biodiversity related traditional knowledge, but the people are not aware of the knowledge vanishing as most of the people are not using such knowledge. Due to this researchers come from different place and take undue advantage. They try to learn all the traditional knowledge and by naming it as research work they try to claim various IPR rights over it especially patent. It is said that now a person of another country knows more about a particular place in Sikkim than the person who is the actual resident of that place.[248]

Sikkim has formulated the Sikkim State Biological Diversity Rule, 2006. The State Biodiversity Board is formed at the state level and Biological Management Committees are constituted at the local level. The main function of the Board is:

- The Board can advice the State Government as per the guidelines issued by the Central Government on matters involving to conservation of biodiversity, sustainable use of it components and fair, equitable sharing of the benefits arising out of the utilization of biological resources,

[248] Information gathered while conducting interview at department of Science and Technology and Climate change at Deorali, East Sikkim at June 12, 2017 at 11:00a.m.

- Board has the power to regulate by granting approvals or otherwise requests for commercial utilization r bio-survey and bio-utilization of any biological resources by Indians,
- To perform such other functions as necessary to carry out the provisions of this Act or as prescribed by the State Government.

The Biological Diversity Act, 2002 lays down various procedures that are to be carried out by person who wants to research on the biological resources, and also a need of prior intimation to the concerned State Biodiversity Board in prescribed from along with the fees. There are many instances when people come without any approval of the NBA and they take away the resources and later do research and claim rights over it. Many cases aren't reported this is because that law is not stringent and the people of a particular place do not recognize the value of the resources found there. This calls for an important task that is to make the people aware about the value of the resources and the knowledge that has been used by them since ages. People must be aware that traditional knowledge provides the leads in identifying the properties of biological resources and enable the industries to develop new products. Even the CBD has given due recognition to States that the contracting parties subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional life styles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge,

innovation and practices.[249] Many interactive workshops are organized by the State Board to discuss the various issues relating to research, bio piracy, illegal trade commercialization especially concerned bioresources and associated traditional knowledge, lack of awareness leading to conflicts of interests, introduction of high yielding varieties of domesticated species and TK. [250] Sikkim Biodiversity Board has also facilitated the construction of 31 Biodiversity Management Committee across the State and mandated them to urgently take up documentation of bio resources and TK in people's Biodiversity Registers (PBRs), identify biodiversity heritage sites and ensure work towards access and benefit sharing agreements with firms or individuals seeking access to their bio resources.

The State Biodiversity Board has released two documents the BMC toolkit and ABS guidelines which is translated into Nepali and also released funds for peoples biodiversity registers documentation of Rs.1.15 lakh each to four BMCs namely Hee-Gyathang BMC(north), Kitam BMC (South), West Pandam BMC (east) and Lingee Sokpey BMC (south). Till today only one PBR has been maintained this must be taken into account that biopiracy issue can be challenged only if the traditional knowledge and other various biological resources are maintained or documented. Most of the traditional knowledge are not written, it is in oral form and conveyed from one generation to another. But the modern society is based on written form. Therefore, to avoid various violations, it must be written down in the people biodiversity register.[251] Maintaining of register is one way of protecting the traditional knowledge from biopiracy. There are traditional knowledge

[249] Convention on Biological Diversity, (1992) Article 8(j)
[250] Sikkim Biodiversity Board committee discusses integration of Cross Sectoral polices, *available at www.scstsenvis.nic.in (*last visited on September 7, 2017
[251] Sikkim Biodiversity Board, *available at Sikkim123.blogspot.in (*last visited on September 23, 2017).

that has been ignored and forgotten, such knowledge system is vital for the well being and sustainable development of a society. The traditional knowledge system has been developed by communities to conserve and utilize the biological diversity of their surroundings. The concept of traditional knowledge must be understood as being very vital to identifying of certain communities who have been following it since ages. There have been many incidents where the traditional knowledge was used for making new products; this takes away the right of the people who have been using it since ages. As the people who have been following the knowledge do not know that the traditional knowledge if used once for making any new product would take away the common rights that they had been enjoying. Though, this issue is highlighted in many debates, discussions and conventions but traditional knowledge as a single entity is not recognized and always linked with some resources. Traditional knowledge must be properly defined and distinguished and a separate law must be framed. There are issues when the people from other place come and visit a particular place and after gaining the traditional knowledge of that place use it for making profits. This is immoral because the people of that place have developed that knowledge and applied it till date so it is unfair when the other people or corporation earn profits from it and without sharing the benefits that are acquired. There are situations where the researcher tries to develop or make something new by using the traditional knowledge of particular communities. The problem arises when the company or the researcher tries to show their sole effort in researching the product or commodity, and claiming all the profits arising out of it. The people, who do not understand about the private rights that are granted by patents thus, feel betrayed as they lose their common rights over the resources that they had been using since ages.

There are number of cases reported regarding this issues but little has been done to prevent it. There are still numerous cases that are to be reported. There were some debate that were held but still a strong legislation hasn't been prepared that would highlight the importance of traditional knowledge and the various methods that are required to stop the misuse of traditional knowledge of a particular community. There are also the problems of benefit sharing which is when the companies or the researcher do not want to share the profits that arise after selling the products that are made by implementing the traditional knowledge. This calls for an important notice to the government to legislate some laws or rules that puts a control to what is known as biopiracy. The biopiracy issues are very much in news but as people aren't that aware about the effects that it has, it is left out as it is. The issue is a grave one because once the traditional knowledge is granted patent the people who had been using it since ages cannot avail the common rights that they were enjoying it. The people who had been using those knowledge still believes that the knowledge should be used by everyone equally but with the advent of IPRs there are certain restrictions that comes along with it. These restrictions aren't familiar to the old people who are using it from old times. This must be noted on behalf of the people as a whole, though detail functions are granted to the Biodiversity Boards but the common people must equally be aware about it. There are numerous instances when the people provide the knowledge unknowingly or in good faith as they aren't aware about the recent developments of the various intellectual rights, so the people give the information but many times it has been misused by the people. This has happened a numerous times especially in places where tourism is one of the means of earning livelihood. In such instances no one can be blamed directly, neither the tourists who get the knowledge about

the traditions nor the people who share the knowledge. So, there is an urgent need to take steps when the acts are done in good faith. Many times the tourists who attain the idea of traditional knowledge for their research work can simply make an excuse of not knowing the laws. So, it's very hard to clearly see how to deal with the biopiracy issues.

As mentioned earlier Sikkim has diverse cultural, traditions and practices, different caste of people follow different practices which they have been following since ages. There is particular type of foods served for particular festivals they have their own traditional dresses and the process to make the same. Not only does Sikkim have diverse cultural and traditions but also the people here use specific varieties of bioresources to treat themselves from diseases. They use the old practices to make some medicines from the plants that are available anywhere near the place; they follow the process to make certain types of medicines. All these knowledge are to be protected safely so that the people who have developed it have the right to use it without any restrictions.

In Sikkim there is a practice of Shamanism (Jhakri, Boongthing, Phedangbo,Maangpa)[252], they are regarded to be knowledgeable people who have vast knowledge they perform rituals during weddings, funerals and harvests. Along with this they diagnose and cure diseases. Talking to such people who have been practising such things from an early age some information was obtained, according to one shaman who has been practising from the age of 12 "the jungle has everything"[253] which means there are huge number of medicinal plants in the jungle and many species that are very valuable but people are not aware about it. Those plants have been used since old times to treat different kinds of

[252] The word is reserved specifically for practitioners of shamanism, such as that practiced among different tribes in Sikkim.

[253] Information gathered while conducting interview with Mr. Nandalal Sharma, Rumbuk, West Sikkim on December 16, 2017 at 1:30 p.m.

diseases. For example for fractures in hands and legs medicinal plants like Ankh (scientific name *Calotropis gigantea*), Chitu (scientific name *Clerodendron infertunaturm)* (both black and white) and Bhuichampa (scientific name *Kaempferia roturela*) are smashed and tied around the fracture. A solution is also made with the help of raw harchur (scientific name *Viscum articulatum*), raw simrip, honey and egg. This is one of the traditional methods that have been used to cure fractures. Other example is the medicines that are made for curing throat ache is kolin tree's root and fruit. The root and fruit are taken by the person having tonsil and chewing it all day long cures the pain. For treating asthma harro pipla's fruit solution is made with honey. For urine problems a plant named bed laure (scientific name *costus specious)* is boiled and afterwards it is mixed with crystallized sugar lumps and drank by the patient this helps to reduce the burns during urinating.[254] For treating severe fever the person is asked to take chirato and nimpati (scientific name *azadirachta indica*) thrice a day. So, there are numerous plants they use to make medicines for different problems, they have cured many people by using it. They avoid going to doctors and trust their knowledge they rely upon their own treatment.

Most of the people practicing shamanism relies upon the medicinal plants that are found in the jungle. Apart from the above mentioned diseases they prepare soup from the plant Sali-bisali (scientific name *equifetum generis*) for treating gouty arthritis these plants are found near streams. Apart from human beings they also have knowledge about treating diseases of animals. One of the plants that are misused by most of the people is cannabis locally known as ganja, it is very effective plant it has numerous medicinal properties and

[254] Supra note 254

can be used for treating various types of diseases in animals.[255] Still today some people approach the person who has the knowledge about various medicinal plants one of the person recalls that he has treated more that 100 people and still prepares the medicine for sinus. For this a plant named pinaasey lahara (scientific name *clematis buchnaniana)* is used[256] the root of the plant is crushed and the patient is asked to smell the solution. According to some people they notice that certain type of plants are no longer found in their places, the plants that were used to treat various diseases are vanishing it is mostly because the people have no knowledge about the medicinal properties of the plants. They fear that with the passage of time there will be very little medicinal plants left. This is an important issue and must be taken into account because once the knowledge is gone it is difficult to learn because most of the knowledge are orally transferred and very difficult to understand. Learning from the elders they mention the names of different plants that were used by their forefathers but they themselves cannot recognize the plants[257]. Today, there are not many people left who use all this kind of methods to make medicines, slowly with the death of the people the knowledge is also dying. It is important that the people who have such knowledge must be respected. Most of them are not so eager to share the information so one must try to make them understand the importance of the TK i.e. importance of their knowledge so that it can be protected**.** To avoid all this there is a need to make a proper mechanism where the knowledgeable people share their knowledge and the officials in turn help to protect the same. There are many more plants that have medicinal properties and according to interviewees there were many people

[255] Information gathered while conducting interview of Mr.Ram Lal Sharma, Naya Bazar, South Sikkim on December 20, 2017 at 2:00p.m.
[256] *Ibid.*
[257] Information gathered while conducting interview of Mr. Passang Lepcha, Rumbok, West Sikkim on December 21, 2017 at 10:00 a.m.

who used the TK to cure snake bites but after their death the method for preparing such medicines are also lost. Now, no one in that area knows how it was prepared. Recalling the old times the people also made a statement that when there were no hospitals the people always relied upon such medicinal plants but now the value of such methods and practices are being neglected, without a proper mechanism to protect it will vanish away or go in wrong hands. The people who have such knowledge are very old and not many young people are interested to learn such methods so it is very important that the Government take initiatives to protect the knowledge and the people who hold such knowledge.

But with the advent of the IPRs the scenario has changed, the idea of private rights are very popular, so the people from outside the place come and try to learn about the TK and by manipulating the genes tag it as invention. This not only takes away the rights of the local people but also it tries to have the sovereign rights over the bioresources that are found only in a particular country. For example as mentioned in the earlier chapter how the plants that had been used traditionally in India were seeked patent rights. All this are not new most of the developing countries that are rich in bio resources are facing this situation. Though initiatives are taken by the Biodiversity Board of Sikkim through the help of BMCs for protection of different kinds of traditional knowledge i.e. literature documentation for (i) oral and medicinal knowledge and (ii) video documentation for folk healers' knowledge and practices. But the main problem with documenting is there are lot numbers of knowledge that are gone out of Sikkim. [258] All this documentation is still

[258] Information gathered from Department of Science and Technology and Climate change of Sikkim, Deorali on June 12, 2017 at 10:00 a.m.

under progress, there are some people who are registered as the traditional healers but they are not ready to talk or share their information.

5.2 Tourism Related Biopiracy

One of the reasons of biopiracy being so prevalent in Sikkim is because of tourism. Tourism is one of the means of employment in Sikkim many people depend on tourism for earning their living. Tourist activities have flourished in Sikkim and have both pros and cons. Many times people come to get the knowledge about particular varieties of resources. They enter the place as tourist and later try to avail all the knowledge and make illegal use of it. It is very hard to control the act of the tourists most of them just deny the fact of them visiting to avail knowledge from the local people. There were cases reported when the tourist who visited Sikkim took away the seeds of the wild varieties of certain plant and started to cultivate the same in his/her place and selling them. So, in such instances how can we make them liable? There are many questions that need to be answered regarding biopiracy issue. We cannot check each and everyone who leaves the State after visiting nor can we ask them not to touch anything as they travel. Many tourists are interested to know the tradition, the culture of the place, and the local people who are ignorant give more information than it is required. Sometimes it can cause damage because sometimes the people acting as tourist could be a researcher, and after availing such knowledge they can use the techniques or by altering the genes of plants claim it as invention to avail rights over it. There is a trend of home stays now a days, the people use their house as home stays and they give the tourist the chance to know the life style, the method of cooking certain dishes, the method of cultivating certain crops, the knowledge of making handicrafts of Sikkim, medicinal value of certain plants. Though it

helps the people to earn some money but there can be some consequences of the same. Recently, there was an incident when the tourist who visited West Sikkim stayed at Yuksam one of the places of Sikkim which holds tremendous traditional knowledge. The person staying took away the seeds of the locally found chilli i.e. *Capsicum annuum* locally known as dalle and planted it at his place USA, after planting it he put the image of the fruit at the social network tagging as American chili. This way the person can sell and earn the benefits that arise out of it and the person to whom the resources belong loses the benefits that they were to get. This is also a case of biopiracy so unknowingly also this takes place and it is hard to make the people liable as in this case.[259]

There are other cases also the case of Atkinson from UK. In this case T.D. Atkinson of United Kingdom was into apparent online sale of seeds of various plants collected from different areas of Sikkim, including protected areas and reserve forests, without permission. The other person was Jhon Mood from Hawai, USA, who was expected to visit north eastern states, including Sikkim, to collect rare and endemic plants for genetic work without approval from the Government of India. After checking the website (http://www.rhodogroup-rhs.org) run by Atkinson. The names of some rhododendron species such as *Decaisnea fargesii*, *Deutzia stamina* and *Elsholtzia flava* were found listed in the seeds up for sale. The website mentioned the names of locations in Sikkim like Lachen, Lachung and Namchi and others forested areas from where the seeds had been produced. So, an advisory notice was issued by Sikkim tourism department against the bio pirates who collected seeds of plants without permission. Previously the tourism department was not asked to get permission from the forest department, but now it is

[259] Information gathered while conducting Interview of Mr. Bharat Pradhan, Sikkim Biodiversity Board Sikkim, on November 2, 2017 at 1:30p.m.

mandatory to avail a pass from the forest department especially when the tourists visit places that are protected. It was not possible to find out whether the local people helped the tourists or not because some people collect wild seeds, insects to sell it to the tourists. This is tuff job for the forest departments also as they get don't know how they take it or with whose help. Most of this happens from the act done in good faith.[260] This should be put to an end. Many times the researcher acts as a tourist and visits the places they visit at a particular seasons and study the entire region and visit such places only when they can collect the information's. After they visit and gather the information they try to take advantage of the information that they have gathered, by doing so they use such resources to make new product and get patent over it. This takes away the rights of the indigenous people who have developed it using their intellect and understanding from a long time. One of the issue in Sikkim is the people aren't self sufficient this is the reason why people open up home stays or give away the resources freely when they earn some money in return. This issue must be taken into consideration as this would lead to biopiracy and no action can be taken as it is done in good faith[261]. There are many instances when the local people share the knowledge about cultivating certain seeds or the benefits of certain plants. The people share such knowledge because most of them don't have the idea of biopiracy, its causes and its effects. When there are such instances the person who takes away the resources cannot be made liable as they always have the excuse of saying that they had no idea about the laws applicable. Even if they are to be made liable the most that can be done is to make them pay the fine, but if the piracy is not known than they need not pay the fine and this way the knowledge that the local people

[260] Sikkim alerts tour operators to bio-pirates-US and UK nationals collect seeds of plants without permission, says forest department*, available at telegraphindia.com* (accessed on November 17, 2017).
[261] Supra note 17.

have developed is misutilized. This not only takes their right to freely use but most of the times they have to pay a price for something that they developed themselves. This also shows that the people aren't aware about biopiracy. Though there are many programs held to spread awareness among the people there seems to be some lacunas that are to be taken into consideration. The local people have specific techniques and they have come up with those after years and years of practices. To give away such rights that they have commonly come up and using it without any restrictions is very unfair.

To stop this there are many initiatives that are taken one of the important steps that are taken by the Biodiversity Board through the BMCs are to maintain the people's biodiversity registers also known as PBRs. This is one of the important initiatives that the government has taken up in compliance to the Biodiversity Act of 2002. It is the duty of the BMCs to maintain a register which has all the flora and fauna that are found in Sikkim. The officials must maintain it and it is a difficult task to gather all the information of not only the bio resources but also the name of people who follow the traditional practices and the traditional knowledge that has been developed and used by the people in Sikkim from ancient times. According to Biodiversity Board officials till now there are 4 biodiversity registers that have been maintained. This is one of the important steps to protect the resources and associated traditional knowledge from biopiracy. Once, all the information are documented there is no chance for the people from other place to come and claim rights over it. But maintaining the register is not easy tasks the officials need to identify the plants, animal's wild varieties of resources and write where they are found and in what ways they are useful and unique. They also need to talk to the elderly people about the traditional knowledge that they have developed and

how they use it. Many times the people aren't so eager to share they mostly deny by saying that they have no idea about all those and this not only covers the truth but also leads a way for biopiracy. This way the knowledge remains unrecognized or undocumented and later if any researchers apply the same methods for making any product people won't be able to show that they had developed it or had been using it for a long time. As mentioned earlier tourism is regarded as one of the ways that leads to biopiracy not directly but indirectly. After talking to some officials at the Biodiversity Board their concern was on how to make the local people aware about the importance of the bio resources available here. The other concern is to inform the tourists about the laws that are available for the protection of the bio resources. Many times they unknowingly take away the resources that they see and later it leads to bio piracy which we cannot report because it's very hard to make them liable for the act of biopiracy as they can always say that they had no knowledge about the laws that were applicable at the place. This way many of the recourses which are part of our culture and tradition go out and sometimes they are commercialized. This way the benefits that gained by trading it are not given to the people.

5.3 Biopiracy: Issue of Prior Informed Consent and Access and Benefit Sharing

The issue of prior informed consent and access and benefit sharing is also prevalent in Sikkim, there are cases when the bio pirates ignore the rules that are laid down under the Biological Diversity Act. The issue was highlighted in various instances and due to which the Guidelines on "Access to Biological Resources and Associated Traditional

Knowledge and Benefit Sharing"[262] Regulations, 2014 was laid down. These regulations provide guidelines to person who intends to access the biological resources and associated traditional knowledge for research or bio-survey and bio-utilization. The researcher needs to apply to the National Biodiversity Authority (NBA) in Form I of the Biological Diversity Rules, 2004 for obtaining access to such biological resource and/or associated traditional knowledge, occurring in India.[263] In case of biological resources having high economic value, the agreement must contain a clause to the effect that the benefit sharing shall include an upfront payment by applicant, of such amount, as agreed between the NBA and the applicant. Under regulation 3 the mode of benefit sharing for access to biological resources, for profitable consumption or for bio-survey and biological uses for utilization is laid down. There is a guideline for sharing the benefit that has been earned after selling the biological resources accessed for commercial utilization. The fees shall be collected by Biodiversity Management Committee (BMC) for accessing or collecting any biological resources for commercial purposes from areas falling within its territorial jurisdiction under sub-sec (3) of section 41 of the Act. The procedure for transfer of accessed biological resources and/or associated knowledge to third party for research or commercial utilization are laid down under regulation 11, and the modes of benefit sharing for transfer of accessed biological resources and/ or associated knowledge to third party for research or commercial utilization is laid down under regulation 12. So, there are various regulations that are laid down under guideline. One of the issues regarding the sharing of benefits is that the biological recourses are

[262] Seeds, Biodiversity and IPRs, available at https://medium.com/@drvandanashiva/seeds-biodiversity-iprs (last visited on November 11,2017)S

[263] Guidelines on Access to Biological Resources and Associated Traditional Knowledge and Benefit Sharing Regulations, 2014.

identified and the benefits can be equally shared but the issue arises when traditional knowledge comes in question. The regulations given in the guidelines are only laid down for the pharmaceutical companies but biopiracy can occur in other ways too as mentioned tourism. This is very important because there are cases when the benefits are not shared with the local people who had been enjoying it from earlier times. Sometimes access and benefiting sharing can also not solve the issue of biopiracy as learnt for the case of Jeevani and the Kani tribes. If the benefits are not shared than it cause the people to lose their collective rights that they were enjoying and also in turn ask them to pay for those resources that were freely available to them. Most recent issue is regarding the illegal taking of Satuwa (*scientific name Paris polyphylla*) which is a medicinal plant that is found in North Sikkim. This plant has wide medicinal use, people use these plants for various medicinal purposes and most people cultivate it for the same but there are people who export this plant from Sikkim. People aren't self sufficient so to earn some money they collect it and sell it to the people who then take it to other countries. This in turn leads to biopiracy. After talking to the officials they were of believe that the local people even after knowing the consequence of being caught with the plant try to do the same. The people have the right to cultivate the same for their private use taking advantage of this the local people hide the fact that they sell the product at much cheaper price to the people who then sell it to other places. Raids are conducted at the people houses but still the main culprits are not caught as many times the people themselves hide that they have collected it. They claim that they are collecting it for their own purpose. In such situation it's very difficult to make the people understand what they are doing isn't correct they don't understand what can be the outcome of bio piracy. The people can lose the right to

freely use, cultivate and sell the seeds once the product is granted patent. Once a patent is granted for the plants that have been traditionally used for medicinal purposes than it is a theft from the indigenous people who have been using it since ages. But, if people don't become aware of the issue regarding biopiracy and patent than it would be a great loss to the biodiversity of Sikkim. The Sikkim Forest Act is only a preventive act where the officials can only prevent the people from doing something wrong where as the other states have Acts that give the officials power to detect crime and also award penalty once they are caught. This is one of the major issues that need to be dealt with and this is possible if some changes are made in the present Acts and then only people will be aware of their rights and duties.[264]

Researchers screening plants for useful substances try to cut down their time of getting information by abstracting the information from indigenous healers who have been plasticizing the same. The indigenous people understand various types of soil and the methods that can lead to resistance of diseases on seeds. So, the companies also collect the sample of soil that is identified by the indigenous communities. The contribution aspect is very highly recognized but the compensation aspect that needs to be awarded to the local communities is very scare. This way the traditional knowledge is facing a numerous threats. The huge part of land, forests and habitat of indigenous peoples and local communities are being affected by a combination of deforestation, logging, road construction and dam projects, mining, urbanization, and conversion of forests to tree and agricultural plantations.[265] This has lead to disruption of the social and ecological context

[264] Information collected during interview with the member of KNPN at Biodiversity Board on November 2, 2017 at 2:00p.m.
[265] Supra note 1

within which the communities have made use of their traditional knowledge. Traditional knowledge in agriculture has also been affected in many developing countries by the conversion from bio diversity based farming system to monocultures promoted through the Green Revolution. The affects can be seen in Sikkim too, previously the farmers had their own seeds, the one that they sowed, harvested and sold themselves. But with the huge development the agriculture system has also changed, seeds are to be purchased from companies and the farmers cannot re use the same they have to purchase it again. The industrial agriculture package of hybrid seeds, chemical fertilizers, pesticides and irrigation replaced the traditional system of farming based on several different crops and many plant varieties that often also combined with fish rearing and other activities. The diversity of seed varieties for each crop, the diversity of crops themselves, as well as the diversity of different types of activities within the same farm or village, has thus been eroded. With this erosion, there is also an erosion of traditional knowledge. So, in this manner the rights that the indigenous farmers have been enjoying are vanishing. The other problem is the type of seeds i.e. genetically modified is neither good for the soil or environment nor for the human health. Talking to some local people who have been practicing the old techniques for agriculture they claim how the products were good and sufficient, when the new varieties of seeds weren't introduced. With new varieties of seeds the production may be high but there is lots of disadvantage of this seeds, the new varieties of seeds deteriorates the quality of soil, and also requires large amount of pesticides and insecticides that does not allow the other crops to grow next time when cultivated.[266] Old method of cultivation are no longer used as most of them follow the

[266] Information gathered while conducting interview of farmers in West Sikkim, Ribdi at September 23, 2017 at 2:30p.m.

modern system of agriculture, but people don't understand that they are losing something more precious, the knowledge that were developed after years of practices and efforts. Not only this but once the seeds are patented the farmers needs to buy the seeds and are not allowed to save and re-use it. The patenting and intellectual property protection of biological resources by private interests has the potential to restrict the ability of producers to use the processes and products relating to traditional knowledge. The local people don't realize but the people from developed countries are trying to learn the old methods that are very effective and easy, and once the corporation or researcher successfully apply for patent over the plants or the biological resources for certain functions, it can prevent others from using the plant or resources. Thus, the person who have been keeping and using traditional knowledge could thus be restricted. Another major issue is the effect the insecticides and pesticides have on the insects that are locally found. The insects that breed naturally are poisoned by the huge amount of insecticides and pesticides. The insects cannot breed naturally and now with new changes in environment condition the insects develop changes. So, the natural habitats also get affected with the new varieties of seeds that are genetically modified for increasing the production rather than the quality. This all leads to misappropriation and potential misappropriation of the knowledge that are held by the local communities and indigenous people who are the rightful owner. The traditional system in most of the countries is that there is no system of private ownership of knowledge regarding the use of biological resources or biodiversity i.e. farming, animal rearing, healing and the use of medicinal plants. Even when there is private ownership of land or the demarcation of rights by different communities to forest areas, indigenous people and local communities have

generally shared their knowledge of the use of seeds, medicinal plants and techniques of production, harvesting and storage, and also shared the seeds and genetic materials. Any kinds of improvement of seeds or innovations were transmitted freely among the local communities. There were thus free access to the genetic materials, knowledge and innovations; although of course the actual materials such as seeds or plants could be traded.[267]

5.4 Biopiracy: Due to Lack of Knowledge

As already mentioned Sikkim has huge bulk of TK that the people have developed themselves using their own intellect and have been using it from old time. The knowledge has been passed on from generation to generation, and are not documented and passed on orally. Though many steps are adopted for protecting it, there is another issue that needs to be highlighted. Biopiracy in Sikkim is taking place due to lack of knowledge and information among the local or indigenous people. Though many workshops are conducted at villages the people seem to not understand the importance of the resources that the place holds. As, already mentioned how people give away the resources to the people who visit their place, not only this people easily share the techniques that have been following since generation. People are ignorant of the biopiracy issue. One of such instance was when the people of North Sikkim were asked to stop selling *Cordyceps Sinensis* also known as yarsa gumba, keera jhar locally and has numerous medicinal properties. It is a rare combination of a caterpillar and a fungus and found at altitudes above 4500m in Sikkim. Traditional healers and local people of North Sikkim recommend it for all diseases as they claim that it improves energy, appetite,

[267] Supra note 2

stamina, libido, endurance, and sleeping patterns. [268] The name cordyceps comes from latin words meaning club and head. The base of the mushroom first originates drom an insect larval host and ends at club-like cap, including the stipe and stroma. The local herders found out that the yak, goat, sheep, etc consuming C.,Sinensis while grazing became very strong and stout. This observation led way for recognizing its medicinal properties. Thereafter, the local people started using to feed the animals for milk production and for improvement of reproductive system. Then soon they started consuming it and also giving it as a gift to people who visited them. It has many medicinal qualities and treats number of diseases like TB, diabetes, cough, jaundice etc. Traditional healers and elderly people use it to increase longevity and cure erectile dysfunction.[269] So, knowing about the value of this most people try to collect it and sell it to people who come to purchase the same. It is very difficult to collect it but people are paid very less for it. Rather than keeping it with themselves and using it for their health benefits they try to sell and earn money. After knowing that the people of North Sikkim were selling the product outside of Sikkim at a very low price and also leading to biopiracy, an awareness programme was conducted for the people and they were asked to collect the keera jhar and that after one year Biodiversity Board would give them the correct price and buy it from them. The people agreed but after some time when the members of the board went to collect the same, most of the families had already sold the

[268] Ashok Kumar Panda and Kailash Chandra Swain, "Traditional uses and medicinal potential of Cordyceps sinensis of Sikkim", *available at https://www.ncbi.nim.nih.gov (*last visited on November 10, 2017)
[269] Ak. Panda, *"Tracing the historical prospective of Cordyceps sinensis-an aphrodisiac in Sikkim Himalaya*," 189-193,Ind J Hist Sci 2010.

products. So, looking at this incident one can make out how difficult is to stop biopiracy from taking place when the people are still ignorant about the value of their resources.[270]

In 2014 mass awareness program was organized by the Biodiversity Board to make the people aware about the importance of bioresources and various issues relating to its protection. The people were also made aware about how old traditions are important; they encouraged and motivated people to conduct some programs that reflect the old cultures and traditions. By doing so the young generations also get to know about the old traditions that were followed by the elders. This is also one of the way in which the people understand the importance of the traditional knowledge and the bio resources that are present in one's place. [271]

The above mentioned are the reasons why biopiracy is taking place, traditional knowledge plays a vital role as it has been the part of our culture and tradition since ages. The people have developed it by using their intellect after various trials; it constitutes a part of their life. Other reason why ample protection cannot be granted to traditional knowledge is because many people migrate to urban areas, with transfer of people, especially the young; the human resources base for the passing on and continued practice of traditional knowledge is being eroded. This is one of the reason why the correct documentation is not being able to be done, many peoples who developed it or who had been using it are dead and when the young ones do not follow or have the knowledge about such practices than there is no way that it can be protected in any form. The other area that needs to be highlighted is the issue of prior informed consent and benefit

[270] Information gathered while interviewing the member of Biodiversity Board of Sikkim at November 2, 2017.
[271] Supra note 271.

sharing that arises out of the resources. Only if the benefits are shared the biopiracy can be done away with. As development is inevitable so it is very important to see that when the resources or the traditional knowledge is being commercialized the benefits that arise should be given to the people who have been practicing and their rights should be acknowledge by getting the prior consent from them.

It is very difficult to point out a perfect solution to provide protection because the officials believe that the Biological Diversity Act is self sufficient to provide protection. But even after having the Act there are a lot number of instances of biopiracy. Most of the cases are said to be off the record but this is not because the officials are lacking, it is because there is no strong or strict legislation. The Act that is applicable in Sikkim is only a preventive one and many times all that can be done is to prevent the person form doing the same, to control issues of biopiracy huge penalty must be awarded. Though there are penalties but hardly there is a culprit who is ready to pay it. So, it is very essential that a strong committee must be set up to see that the culprits are caught and awarded penalties for the same. Most of the people don't understand the concept of traditional knowledge, biopiracy all they understand is to earn some money anyhow so the people must be made aware about it. The BMCs of every district must work effectively only one BMC cannot stop the issue of biopiracy by maintaining a register every committee must be efficient and fulfill the duty.

CHAPTER 6

CONCLUSION AND SUGGESTIONS

Biopiracy takes place when the research is done without seeking the permission and consent of hundreds of thousands of indigenous people who have developed the knowledge for generations. The Biological Diversity Act, 2002 states that, if companies want to genetically modify indigenous varieties of seeds and plants for research or commercialization purposes they must obtain prior consent of the authority. Local communities or indigenous people must be consulted and remunerated when companies use indigenous crop and seed varieties that local farming populations have cultivated and protected for generations.

"With the advent of IPRs and the concept of patent rights there is always a terror that somebody else may obtain right over the ownership, trade and market the commodities that are available at a particular place. The examples are what happened not far back with the traditional knowledge based on neem, basmati, haldi and so many other Indian goods. The municipal laws have taken an imitative to protect its indigenous community's rights and traditional knowledge through legislations but these has not been sufficient enough to deal with the issues of biopiracy. There is an urgent need of an 'umbrella' legislation that would govern the entire landscape of Indigenous Community and their TK.

Even the patent laws should reflect the rights of the indigenous people who are the real inventors, they have the right of self determination of their future, so the patent laws must bring about necessary changes, than following the out dated western definition of "invention" that is by manipulating genes. The Indigenous people should have the right to

information connected to security of their traditional knowledge. Both morality and justice demand that the developed countries treat Indigenous people of developing countries with respect, as they are the true owner of the knowledge that the developed countries claim patent on. The indigenous people must be supported by national and international laws, instrumentalities and so they can have equivalent foothold at the negotiation desk."[272]

As already mentioned in preceding chapters the importance of traditional knowledge, the impact of biopiracy and the various legislations that are implemented to look into the various issues need to be examined. There are not many provisions for protection of traditional knowledge and it must be given utmost priority. The problem is that traditional knowledge is recognized only as a part when we discuss about protecting the biodiversity of particular place. The concept of traditional knowledge must be defined clearly and the laws should be specifically made for its protection. More strict laws need to be framed for protecting the traditional knowledge and the rights of knowledge holders. Traditional knowledge also contributes to the general knowledge on sound environmental principles and management, such as in forest conservation, soil conservation, seed conservation and crop biodiversity. The contributions of traditional knowledge to human development, especially in food production, crop yields and health care are to be recognized. But the researchers or the big multinational corporations are trying to make profit by using the traditional methods, techniques of a particular place. Though, most of the people know that traditional knowledge is important and it is very necessary to protect the same but there have been no serious steps for the protection of same. There are cases of biopiracy

[272] Supra note 17.

and many times they claim private rights over the research that they make by using the traditional knowledge. India being the member of TRIPs has enacted legislation that is TRIPs compliant hence the protection measures of traditional knowledge also should be taken into consideration. India is a developing country and hence development is must but with emerging IP rights if the rights of indigenous people is being violated than the Government must look into other ways through which the rights of the people are being safeguarded. One of the important steps that India took was framing the TKDL. This has helped India to claim the rights over the traditional medicines of various plants. After the formation of the TKDL there is decline on the cases of biopiracy. But, it has some drawbacks; the library mostly contains information of traditional medicinal properties of plants. The methods for cultivation of particular crops, the particular breed of seeds that are cultivated by particular communities since ages has to be protected too. Even the benefit sharing provisions given under the Biological Diversity act provides guidelines only for resources that are being used by the pharmaceuticals companies. The other areas such as the traditional knowledge is not covered under it, this way the protection measures especially for the traditional knowledge is lacking.

Suggestions

After studying the scenario of traditional knowledge in Sikkim, it seems more stringent steps need to be taken by the Government and the concerned authority. Moreover, the rights of local communities need to be recognized and respected widely. More importance must be given to the role played by traditional knowledge and should be recognized that only if the traditional knowledge is maintained the social and economic development is possible, and for the economic and social context to be maintained the

rights of the local communities to their resources and knowledge has to be acknowledged. The sustainable development must be encouraged as misappropriation could lead to loss of rights over traditional knowledge. This can be done by strictly following the benefit sharing provision under the Biological Diversity Act, 2002.

It is important that the domestic law must have requirements for prior informed consent of TK holders (indigenous and local communities) on mutually agreed terms implying benefit sharing which is discussed in Article 12 of Nagoya Protocol. It is the traditional knowledge that leads the research of new products hence, the benefit must be shared.

After going through all the cases of biopiracy one important suggestion that can be adopted is for better examination of patent applications to ensure that they are truly novel and that they take into account the prior art as it exists in other countries. Developing countries have intellectual properties that are worth protecting. This can be done by harmonizing IPR laws, because biased IP safeguard generates unfair commercialization because IP protection is the strongest. The rich countries should eliminate patentability of plants and make a requirement to disclose traditional knowledge .A continuous support for documentation of traditional knowledge that is mostly oral is required**.** This way the knowledge is placed in the public domain and so if any patent claim is made the patent granting authority (like USPTO) can see through it and also prevent commercialization of traditional knowledge. The diversity of knowledge needs to be recognized and respected, and a pluralistic IPR regime needs to be evolved which would make it possible to recognize and respect indigenous knowledge and protect the indigenous knowledge, systems and practices and livelihood based on it.

Based on the laws that are applicable in Sikkim we find that Traditional knowledge is not protected as such, for this to be vigorously protected certain laws needs to be amended. There are many nations that have opted for Sui Generis protection; same can be done for the traditional knowledge protection all over India.

Outsiders with intention to research know a lot and they use the ignorance of local people for stealing the knowledge that indigenous people have. Though, the Forest Department, the Biodiversity Boards and the Biodiversity Management Committee of Sikkim are doing their best either at preventing, controlling or spreading awareness among the people. But if peoples' cooperation is not there than this issue cannot be controlled. Though the Biological Diversity Act, 2002 talks about the protection of traditional knowledge but there are neither specific definition of word traditional knowledge nor any mention of the word biopiracy. So, it is difficult to try the same directly for the biopiracy issue without knowing it constitutes a crime or not. For this the biopiracy issue must be put in more light and the definition of traditional knowledge, the protection that it needs, the measure to protect and the remedies that one can be awarded if someone commits biopiracy on traditional knowledge of any kind must be laid down. One of the reasons that the biopiracy cases are off the record in Sikkim is because the acts that are available for the protection of traditional knowledge or the bio resources are old and the biopiracy is new. So, some sort of amendments must be made.

Most importantly, the people must be made more aware about the value of the traditional knowledge and the available bio resources in our State. Though, many initiatives are taken by the Biodiversity Board there are still many places where people aren't aware. The local people are busy earning money for themselves and while doing so they do not

realize they are trading the valuable resources and the traditional knowledge that are very important for the identity of Sikkim as a whole. This type of easy thinking must be changed and in doing so more people must be made aware about the importance of biological resources and the associated traditional knowledge. The other way of making the people aware is by organizing such awareness program at schools, and colleges by doing so the young generation can all be aware and they can convey such messages to their elders who cannot go to such programs.

As already mentioned that tourism also leads to biopiracy so to control it the people who are engaged with tourism activities must also be made aware about the various Laws and the penalties that can be awarded if biopiracy takes place with the help of the local people. Many times the researcher may hide their identity to pass the boundary; they can later abstract the knowledge and the resources from the people. Everyone should be made aware of the situations that can arise when the fake person enter as the tourists. So, the checking must be done more cautiously and they must also have the duty of making the tourist understand that they cannot do any acts that could cause any damages to the property, integrity of the place that they are visiting. Another step that can be taken is that the young people who have taken up the job of guide must have the knowledge of the Acts i.e. Forest Act, Biodiversity Act etc. This way they can be aware of the laws and can also make the tourists of the consequences if they find something suspicious. One of the important reasons of Biopiracy is that the people aren't aware of this so only if they themselves are educated about the rules and regulations than only they can protect the resources and tradition of our place.

The people who are engaged in the activities of home stays must also be informed about the Acts so that they can also frame some guidelines for the tourists who come to stay there. They can explain them that they cannot take away the knowledge either in written form or take away the resources along with them. As already mentioned that there were lots of biopiracy issues when the act was done in good faith and no actions could be taken. But if the tourists are informed before hand and even if they don't follow the same than they can be made liable. So the people running home stays should also make themselves aware about all the situations.

Most of the cases regarding biopiracy were handled by the officials of the Forest Department of Sikkim, one of the reasons that all those cases are off the record is because of lack of evidence and the jurisdictions are also lacking. The Forest Act of Sikkim needs to be amended because it is very old act and the issue of biopiracy is new. For effective trials of such cases, the Acts must be either amended or implemented. Moreover with the increasing instances of biopiracy the forests officials are entrusted with the duty to look into the paper of every tourist who enter the place and they must be very alert and try to keep a close eye on the people when they feel suspicious about them.

APPENDIX 1

Questionnaires prepared for conducting interview of the Members of the Biodiversity and some traditional knowledge holders.

Questions

1. **In what ways the TK of Sikkim is protected and is the protection provided enough?**
2. **What are the major issues to be highlighted when we talk about the protection of TK?**
3. **Is there any cases of biopiracy and how was it dealt?**
4. **What are the necessary changes that need to be adopted for protection of TK from biopiracy?**
5. **Apart from laws what needs to be done so that the people become aware about the importance of TK.**
6. **Can we deal the biopiracy issue with the help of existing laws?**
7. **How PBRs are helping in Protection of TK and TK holder?**
8. **Is the BMCs functioning well as they are entrusted with important functions i.e. for documentation of TK?**
9. **How can we take actions for the unintentional acts done which results to loss of the biodiversity?**
10. **Why is there an urgent need for protection of TK in Sikkim?**
11. **In what ways TKDL is helpful to Sikkim?**
12. **How can we make people liable for the act already done i.e. taking away of the resources that are found only in Sikkim?**

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