

# DISSERTATION

Biopiracy on Medicinal Plants In India: A Study on Securing Sustainable  
Rights

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## **SUBMITTED TO**

INSTITUTE OF LAW, NIRMA UNIVERSITY

*AS A PARTIAL FULFILLMENT OF REQUIREMENT FOR THE  
DEGREE OF MASTER OF LAW (LL.M)*

## **UNDER THE GUIDANCE OF**

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# TABLE OF CONTENTS

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1. DECLARATION	4
2. CERTIFICATE	5
3. ACKNOWLEDGEMENT	6
4. LIST OF CASES	7
5. ABBREVIATIONS	8

## CHAPTER 1: -

1. INTRODUCTION	
1.1.Introduction.....	9
1.2. Statement of Problem.....	10
1.3.Literature Review.....	10
1.4.Aims of Study.....	10
1.5.Significance of Study.....	13
1.6.Scope of Study.....	13
1.7.Research Questions.....	14
1.8.Hypothesis.....	14
1.9.Research Methodology.....	14
1.10. Chapterisation.....	14
2. CONCEPTUALISING BIOPIRACY	
2.1.Bioprospecting and Traditional Knowledge.....	17
2.2.Biopiracy.....	19
2.3.Bioprospecting and Biopiracy.....	21
3. INTERNATIONAL FRAMEWORK	
3.1.World Intellectual Property Rights.....	23
3.2.Trade Related Aspects of Intellectual Property.....	25
3.3.Convention on Biological Diversity.....	28

3.4.Nagoya Protocol.....	31
4. ACCESS AND BENEFIT SHARING	
4.1. Access and Benefit Sharing.....	35
5. MEASURES TAKEN BY INDIA	
5.1.Challenges faced by India.....	39
5.2.Biodiversity Act, 2002.....	41
5.3.Traditional Knowledge Digital Library.....	45
6. BIOPIRACY AND JUDICIAL CASES	
6.1 Turmeric.....	50
6.2 Neem.....	51
6.3 Indian Ginseng case.....	53
6.4 Jamun.....	54
6.5 Colgate-Palmolive Case.....	55
6.6 Divya Pharmacy v Union of India.....	56
7. CONCLUSIONS.....	59
8. BIBLIOGRAPHY.....	62

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# DECLARATION

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I, Riya Gupta, bearing roll no. 19ML021, do hereby declare that the dissertation submitted is original and is the outcome of the independent investigations/ research carried out by me and contains no plagiarism. The dissertation is leading to the discovery of new facts/ techniques/ correlation of scientific facts already known. This work has not been submitted to any other University or body in quest of a degree, diploma or any other kind of academic award.

I do hereby further declare that the text, diagrams or any other material taken from other sources including [but not limited to books, journals and web] have been acknowledged, referred and cited to the best of my knowledge and understanding.

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# CERTIFICATE

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This is to certify that the dissertation entitled Biopiracy on Medicinal Plants In India: A Study on Securing Sustainable Rights has been prepared by Riya Gupta under my supervision and guidance. The dissertation is carried out by her after careful research and investigation. The work of the dissertation is of the standard expected of a candidate for Master of Laws [LLM] in Criminal Law and I recommend it be sent for evaluation.

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## ACKNOWLEDGMENT

I would like to acknowledge Dr Bishwa K Dash for guiding my dissertation work. Further I would like to express my gratitude to my teachers at Institute of Law. Lastly I would like to thanks my family for their support.

## LIST OF CASES

- Turmeric patent revocation
- Neem patent revocation
- Indian Ginseng patent revocation
- Jamun patent revocation
- Colgate-Palmolive patent revocation
- Divya Pharmacy v Union of India, Writ Petition (M/S) No. 3437 of 2016

## ABBREVIATIONS

ABS	Access Benefit Sharing
BD Act	Biological Diversity Act, 2000
CBD	Convention on Biological Resources
CSIR	Council of Scientific and Industrial Research
EPO	European Patent Office
FAO	Food and Agriculture Organisation
GATT	General Agreement on Tariff and Trade
IGC	Inter Governmental Committee
IK	Indigenous Knowledge
IPO	Indian Patent Office
IPR	Intellectual Property Rights
NBA	National Board of Approval
NGO	Non Governmental Organisation
PCT	Patent Cooperation Treaty
PLT	Patent law Treaty
SBB	State Biodiversity Board
TK	Traditional Knowledge
TKDL	Traditional knowledge Digital Library
TRIPS	Trade related aspect of intellectual property rights
U.S.A	United States of America
UK	United Kingdom
UN	United Nations
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation



## CHAPTER 1: INTRODUCTION

Title: Biopiracy in medicinal plants in India: A study towards securing sustainable rights.

Area related: Sustainable development and India's response

### 1.1 Introduction

Since earliest times, plants have played an important role in the sustenance of human life, be it as a source of food, medicines or as part of their ritual and religious ceremonies. Utilisation of plant as nature's resource to satisfy human needs have been documented in form texts or is passed from generation to generation verbally or as cultural practice. India being culturally and ecologically diverse country is a home of different species of plants that find their reference in Indian mythology and religious texts. One such example are the Vedas, that depict co-existence of nature and human life, be it in a form of ritual to be performed, an element to worship or utilisation of its resources in form food or as medicine. Charaka Samhita, Shruta Samhita are other examples, where plant resources are utilised to satisfy the human need in form medicines. Thus contributing to India's plant based medicinal practice of Ayurveda, others being Unani and Siddha that together meet the health care needs of majority population of the country that includes poor and people from tribal communities. Thus communities are one of the stakeholders of this traditional system of medicines, who not only use these plant based system as healing agent, but it also serves as means of their livelihood as practitioners or producers.

## 1.2 Statement of problem

Traditional plant based medicinal system serves the health care needs of majority population in India. Further, this system has proved to have fewer side effects and is capable of dealing with the problem of body being resistant to certain drugs, as happens with allopathic drugs. Thus there is rise in demand for these natural alternatives along with rise in health consciousness among people. Hence the knowledge pertaining to the use of medicinal plants is not only confined to a particular community or people, but has spread across the globe fostering countries in advancing technology for extracting and utilising plant resources for medicines. Thus we find more and more pharmaceutical companies, manufacturers and researcher, producing and developing medicines from medicinal plants. However, sometimes in doing so they often ignore the interest of the communities who are major stakeholders of that particular medicinal plant or possess knowledge of its medicinal usage, that is passed within generations, from one to other amongst the communities. Thus, when these communities are deprived off the benefit of their knowledge or contribution it amounts to biopiracy, thus hampering the sustainable growth and development. Hence one of greatest challenge in globe and in India is to curb this biopiracy that hinders the development one at the cost of other.

## 1.3 Literature review

### Books

- The Plunder of Nature and Knowledge Biopiracy by Vandana Shiva

This book gives an account of practice of biopiracy in India. It criticises how the practice of biopiracy has been resorted by the companies, nations that fosters their

own development, depriving countries like India especially Indian framers and cultivators of the benefits they are deprived off. It describes about the socio-economic outcomes of biopiracy.

- **Confronting Biopiracy by Daniel F. Robinson**

This book gives an account of international legal backdrop pertaining to biopiracy at international level. It elaborates about international treaties and conventions pertaining to biopiracy. It further gives examples of both patent based and trademark based biopiracy case across different countries such as Mexico, Brazil etc.

#### Articles

- **Pharmaceutical Biopiracy and Protection of Traditional Knowledge by R.D. Singh, S.K. Mody, H.B. Patel, Sarita Devi and D.R Kamani.**

This article elaborates on biopiracy in medicinal plants and related traditional knowledge. The article gives a brief account of international framework pertaining to biopiracy especially focuses on Convention on Biological Diversity and Nagoya protocol. Later it discusses Biological diversity Act, 2003 and Traditional Knowledge Digital Library as India's initiative to combat biopiracy.

- **Fighting Biopiracy: The Legislative Protection of Traditional Knowledge by Javier Garcia.**

This Article evaluates the TRIPS Agreement as facilitating innovations though biological resources. It further criticises TRIPS Agreement as means of biopiracy in developing nation Mexico. It further proposes changes to be brought in this Agreement along with Mexico's patent regime.

- Bioprospecting or Biopiracy: Does the TRIPS Agreement Undermine the Interests of Developing Countries by Lowell Bautisa
- This article gives a legal backdrop of the international agreements and conventions. The article compares the provisions of TRIPS agreement with the provisions of Convention on Biological Diversity and brings out benefits and loopholes in each of them in light of benefits to the developed nations like U.S.A. It further gives example of cases like patenting Enola Bean plant of Mexico, Neem and Turmeric case from India.
- Access, Benefit Sharing and Intellectual Property Rights by Bishwajit Dhar and R.V. Anuradha

This article elaborates on intellectual property rights, how they besides offering protection also become tool of biopiracy, it gives insight about access and benefit sharing under Convention on Biological Diversity and Nagoya Protocol can serve as one of the means of combating. It further brings out shortcomings of the access and benefit sharing system and its implementation in Indian scenario.

- Addressing Biopiracy through an Access and Benefit Sharing Regime by Oluwatobiloba Moody.

This article analyses the Access and Benefit Sharing Regime as means ensure Fair and Equitable benefit sharing for sustainable development by developing a the challenges they face while combating biopiracy through Access and Benefit sharing Regime. It further discuss on measure taken by WIPO can be combined with Access and Benefit Sharing to combat bio piracy.

- Combating Biopiracy- a legal way by Kasturi Das

This article analyses the various initiatives taken by India to combat biopiracy.

#### 1.4 Aims of the study

The study undertaken has the following aims:

- 1 To understand the problem of biopiracy and measures undertaken to curb it.
- 2 To understand how biopiracy has resulted into unequal development.

#### 1.5 Significance of the study

The research undertaken would serve useful in understanding the problem of biopiracy and its impact on developing countries like India. It helps in studying the existing legal framework that needs proper understanding for conferring protection against biopiracy. Further helps in understanding and analysing the measures taken by India in protection of medicinal plants the practice of biopiracy and resource depletion. Thus help in discussing about the issue, which remains untouched or ignored by the various stakeholders, conservatives, people and interest groups such people having knowledge about the use and medicinal properties of such plants.

#### 1.6 Scope of Study

The scope of study is confined to biopiracy in respect of medicinal plants in India. The researcher will discuss about cases of biopiracy in India along with existing legal framework. Further the researcher will give an overview of international legal framework that will largely concern with patents.

### 1.7 Research Questions

1. Whether there exists a legal framework for protection for curbing biopiracy at global level?
2. Whether, India has taken any steps to curb the biopiracy?

### 1.8 Hypothesis

1. The protection extended under TRIPs agreement is biased towards nations having stronger legal system and ineffective.
2. Convention on Biological Diversity is a mere a paper regulations.
3. India is successful in curbing the cases of biopiracy of medicinal plants.

### 1.9 Research Methodology

The study undertaken by researcher is adopted doctrinal study, where the researcher has relied in books, and articles as e-resources as secondary sources of information.

The researcher has relied to statutes, which serve as primary source of information. It is descriptive and qualitative in nature.

## CHAPTER 2: CONCEPTUALISING BIOPIRACY

## Introduction

Biopiracy involves piracy of biological resources, where biological resources may mean any living organism or component, which has a potential to satisfy human want. Whereas, as per Convention on Biological Diversity, it includes genetic resources, organism or parts thereof, population, or any other biotic component of ecosystem with actual or potential use or value.<sup>1</sup> This Convention is also significant step in conservation of biological resources and also a measure to curb the practice of biopiracy. One of the earliest measure regarding conservation and sustainable use of biological resources or bio-resources was initiated in the Stockholm Declaration in year 1972. Recognising the ideals of this declaration, the United Nations adopted sustainable developmental goals that emphasised not only on resource conservation but also facilitated technological innovation that includes innovations using biological resources. Thus, this facilitates prospecting activities being undertaken in biological resources.

### 2.1. Bioprospecting and Traditional Knowledge

Bioprospecting is defined as a search for plant or animal species for deriving a medicinal drug or for obtaining compounds that are commercially valuable.<sup>2</sup> While, the origin of the term bioprospecting can traces back to year 1993 when the World Resources Institute defined it as ‘the exploration of biodiversity for commercially valuable genetic and biochemical resources’.<sup>3</sup> However, the practise of bioprospecting is even older then its origin. Earlier hunters and gatherers used to search for plant and animal species that would

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<sup>1</sup> UN Convention on Biological Diversity, art 2, June 5,1992, UNEP

<sup>2</sup> *Bioprospecting*, The Collins Dictionary, (last visited June 3, 2020), <https://www.collinsdictionary.com/dictionary/english/bioprospecting>

<sup>3</sup> Daniel F. Robinson, *Confronting Biopiracy*, 11(Earthscan 2010)

satisfy their food and medicinal requirements. Thus led them to explore more, thus making them aware of the uses, properties of the flora and fauna around them. This knowledge gathered was then passed on from one generation to another, thus become intellectual resources of the community, which is termed as Traditional Knowledge (TK). This term traditional knowledge also includes knowledge about the characteristics of plants having healing properties that have been used and developed by the communities through thousand years of experience, trial and errors and generation-to-generation refinement. These communities or indigenous societies often observe the norm of sharing and exchanging such knowledge about biodiversity. Later, when discovery for newer lands became a norm, the merchant and trader carried back with them this knowledge along with plant resources in form spices, medicines etc., this lead to development of new field of study called ethno botany, which can defined as a scientific study, which involve study of traditional knowledge, customs of people concerning plants and their religious, medical and other uses.<sup>4</sup> Thus trading of plants by merchant and traders is one example of bioprospecting. However with colonisation this earlier form of bioprospecting, where both resource provider and the user benefitted, became subject of colonisers, who would disregard the rights and deprive benefits to the indigenous people/ community. Today, in era of technology, industrialisation, where sovereignty, freedom and idea of sustainable development is paramount, issue regarding ownership of resources and TK remains the same. The plant resources and TK that were subject of coloniser have become a monopoly right of pharmaceutical companies, industries through Intellectual Property Rights (IPR's).

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<sup>4</sup> *Ethno botany*, The Oxford Dictionary, (last visited June 3, 2020), [www.oxfordlearnersdictionaries.com](http://www.oxfordlearnersdictionaries.com)



Hence, these freely exchanged resource knowledge become a private property from being biological commons.<sup>5</sup> Thus gave rise to the problem of biopiracy.

## 2.2. Biopiracy

Biopiracy is a process where rights of indigenous cultures over resources and to knowledge is extinguished and is replaced by monopoly rights of those who exploit such knowledge and resources it<sup>6</sup> thus, the *individual*, companies or organisation that indulge to practice of biopiracy are termed as biopirate and they refrain from sharing the benefit arising from such knowledge and biodiversity with the indigenous community or people. However a Canadian NGO Rural Advancement Foundation International particularly attributed to activist Pat Mooney, on growing monopolisation and appropriation of medical and agricultural knowledge about plants, animals and on them as physical resource. The Organisation defined biopiracy as the appropriation of knowledge and genetic resources of farming and indigenous communities by individuals or institutions who seek exclusive monopoly control over these resources and knowledge.<sup>7</sup>

Biopiracy can be classifies into three categories based on the method adopted that are<sup>8</sup>

2.2.1. Patent based biopiracy: where inventions based on biological resources and /or traditional knowledge is patented and this knowledge is extracted or such resources are used without benefit of sharing and appropriate authorisation from other countries, indigenous or local communities (mostly from developing countries).<sup>9</sup>

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<sup>5</sup> Vandana Shiva, *The plunder of nature and knowledge Biopiracy*, xviii (Natraj Publishers, 2012).

<sup>6</sup> *Supra*

<sup>7</sup> Daniel F. Robinson, *Confronting Biopiracy*, 18 (Earthscan 2010)

<sup>8</sup> Daniel F. Robinson, *Confronting Biopiracy*, 21 (Earthscan 2010)

<sup>9</sup> *Supra*

2.2.2. Non- patent biopiracy: where biological resources and/or traditional knowledge is extracted without benefit sharing and adequate benefit sharing from other countries, indigenous or local communities through other IPR such as trademark, plant variety.<sup>10</sup>

2.2.3. Misappropriations: the unauthorised extraction of biological resources and traditional knowledge for purpose of carrying out research and development from the other (usually developing) countries, indigenous or local communities, without adequate benefit of sharing.<sup>11</sup>

Here authorization means getting (free) prior informed consent from the government authorities and where relevant, local communities or other providers.<sup>12</sup> Whereas as per writer Vandana Shiva biopiracy can take place through 3 levels that are:-

2.2.4. Resource piracy: where biological resources are freely taken without the permission or recognition of the communities or country.

2.2.5. Intellectual piracy: where without giving recognition or taking permission of the communities or country, their cultural and intellectual heritage is used through IPRs such as trademark.

2.2.6. Economic piracy: In which there is usurpation of domestic and international markets through IPR and trade names. Thus destroying the economy, where originally the innovation had taken place. For example Country A usurp the Country B's market for selling a plant-based medicine, which is innovated by Country B' small-scale producers.

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<sup>10</sup> *Supra*

<sup>11</sup> *Supra*

<sup>12</sup> Daniel F. Robinson, *Confronting Biopiracy*, 21 (Earthscan 2010)

### 2.3. Bioprospecting and Biopiracy:

It is often argued that bioprospecting can become foundation stone of biopiracy, especially when the benefits of bioprospecting activity are deprived to those, whose knowledge or resource is appropriated. Even though bioprospecting has potential to contribute in sustainable development by ensuring growth of national economy, its people including indigenous communities but negative impact cannot easily ignored such as destruction of biodiversity, its harmful impact on local communities, markets and indigenous people. In such case bioprospecting a prior stage to biopiracy where bioprospecting activities of pharmaceutical companies and ethnobotanist becomes threat to biodiversity and traditional knowledge of indigenous territories and people, where they reap profit from the same without acknowledging the contributions bestowing benefits to the indigenous people and to their territory.

With rise in demand for drugs having minimal side-effects, pharmaceutical companies to have incur high expenditure in research and development of drugs that have less side effects. Hence these companies often resort to TK based bioprospecting that may significantly cut down costs as well as the products ascertain would also provide solution for minimal side-effects and drug resistance. Thus pharmaceutical industries are looking for the medicines and products that are developed by the local or indigenous communities in countries like India, China and Africa where centuries old techniques

and traditions of healing through plants and forest produce are still in practice, hence countries like these often become hunting ground of biopirates.<sup>13</sup>

When it comes to dependency of pharmaceutical industries and medicinal plants. It is observed that large pharmaceutical industry derive large sum of their revenue that is around 250 billion US dollars annually from drugs directly derived from plants based medicines.<sup>14</sup> It is observed that 62% of cancer drugs that are approved by the US Food and Drug Administration come from or are modelled based on natural products.<sup>15</sup> Nearly 40% of drugs in the clinical phase are derived from plants.<sup>16</sup> However, such bioprospecting activity by the pharmaceutical companies may result to biopiracy when such companies make use of medicinal plants or traditional knowledge relating to it by enjoying benefits from the same without acknowledging the indigenous community or by giving them with little or nothing in return. Thus in order to have sustainable and mutually beneficial relationships between these pharmaceutical industries and the concerned community, there should be fair and equitable collaborations and ventures undertaken between them, which would ensure benefit to all and also take into consideration the existence of particular plant or herb is not exposed to threat or extinction.

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<sup>13</sup> R.D. Singh, S.K. Patel, H.B. Patel, et.al, *Pharmaceutical biopiracy and protection of traditional knowledge*, 3(2) Int. J. Res. Dev. L. Sci. 867(2014).

<sup>14</sup> *Supra*

<sup>15</sup> *Supra*

<sup>16</sup> *Supra*

## CHAPTER 3: INTERNATIONAL FRAMEWORK

Intellectual Property Rights such as patents, trademarks are major tool creating the problem of biopiracy. When it comes to medicinal plants, generally patents have served mechanism for biopiracy. The TRIPS agreement under General Agreement on Tariffs (GATT) and Trade provided patent protection for innovations that includes the field of biotechnology. This was followed by adoption of Patent Cooperation Treaty (PCT) and later Patent Law Treaty. The Convention on Biological Diversity in 1992 and Nagoya Protocol later introduced access and benefit sharing system, that facilitated utilisation of biological resources and knowledge related to them amongst the countries and prevent indulgence in practice of biopiracy. In this chapter, the international attempts made in respect of prevention and curbing biopiracy will be discussed.

### 3.1. World Intellectual Property Organisation

World Intellectual Property Organisation (WIPO) is the specialised agency of United Nations Organisation with 189 states as member. Organisation's mission is to lead development of balanced and effective international intellectual property system, which facilitates innovation and creativity that is beneficial to of all members.<sup>17</sup> The

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<sup>17</sup> World Intellectual Property Organisation, *Inside WIPO* (July 21,2020), <https://www.wipo.int/about-wipo/en/>.

organisation acts as a driving force for harmonising intellectual property standards and international level.

In year 1970 the Patent Cooperation Treaty and in year 2000 Patent Law Treaty were enacted in order to facilitate harmonization of patent laws internationally. In the year 2000 the Committee on Intellectual Property Genetic Resources, Traditional Knowledge and Folklore (IGC) was created that was instructed to address issues pertaining to the intellectual property aspects of biological resources and traditional knowledge. The committee was formulated on the proposition by the developing countries to adopt requirement of making disclosure for the patents that are derived from genetic resources in the Patent law Treaty. This conferred an obligation upon patent applicant to disclose and prove that country to which such genetic resource belongs has given him permission to procure access to genetic resources. The committee in its first session had worked upon contractual clauses for access and benefit sharing that would serve as model, creation of Traditional Knowledge Database, Prior art status and formulation a way of giving legal protection to Traditional Knowledge.

In year 2005 the committee made an attempt to develop ideas for development of customary laws for the protection traditional knowledge and cultural expressions of folklore. In its thirteenth session in year 2008 the committee had consolidated working documents on protecting cultural expressions and traditional knowledge. It also had set of recommendations for recognition of traditional knowledge within patent examination.<sup>18</sup>

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<sup>18</sup> Daniel F. Robinson, *Confronting Biopiracy*, 33(Earthscan 2010)

However the committee attracted criticism in the grounds that it lacked progress on substantive mechanism for the protection of biopiracy though it was successful in developing new understanding and approaches in respect of traditional knowledge.

### 3.2. Agreement on Trade- Related Aspects of Intellectual Property Rights (TRIPS)

This agreement is regarded universally to be the most comprehensive international agreement on intellectual property rights.<sup>19</sup> TRIPS was adopted in Marrakesh on April 15, 1994 within the framework of Uruguay Round into the General Agreement on Tariffs and Trade (GATT). It came into force in year 1995 and is multilateral agreement by signatories under World Trade Organisation (WTO). Thus it is to be abided by the members, who are the member of or wishes to accede the WTO. The agreement expands and builds upon the obligations that are substantive of the main conventions of the WIPO, the Paris Convention and the Berne Convention. The agreement covers rules or provision in respect of trademarks that includes service marks; copy right and related rights; industrial design; geographical indications; the layout designs of integrated circuits and undisclosed information including trade secrets and test data and patents that includes the protection of new varieties of plants.<sup>20</sup>

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<sup>19</sup> Lowell Bautista, *Bioprospecting or Bio piracy: Does the TRIPS Agreement undermine the interests of developing countries*, 82(1), Phil. L. J. 17(2007).

<sup>20</sup> *Supra*

Article 27 is an important article pertaining to issue of biopiracy, which enumerates upon subject matter that can be patented . As per Article 27 of the TRIPS Agreement a patentable subject matter must fulfil the criteria of being new (Novelty), involving an inventive step (Non obviousness) and being capable of industrial application.

In the paragraph 2 of Article 27 the members are empowered to exclude from patenting inventions on the grounds of conferring protection to animal, human or plant life or for their health or for purpose of avoiding prejudicing the environment. Further patent can excluded for the purpose of preventing commercial exploitation within their territory so as to protect public order or morality. In paragraph 3 members may also exclude from granting patents on methods that are diagnostic, therapeutic and surgical used for treating humans or animals; animals and plants other than microorganisms, and e biological processes that are essential for the production of plants or animals excluding non-biological and microbiological processes.<sup>21</sup> However, agreement provides that members are required to provide protection to plant varieties either by an effective sui generis system or by patents or by any combination.<sup>22</sup>

With the change of era from chemical era to the age of biology has brought new problems regarding patentability. Firstly the patents on biodiversity or products or uses of biodiversity such as claim on medicinal properties of plants as ‘product of mind’ instead of ‘products of plant biodiversity’. The plant-based medicines are not merely a result of inventive human genius unlike the mechanical and electrical artefacts but are

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<sup>21</sup> The Agreement on Trade-Related Aspects of intellectual Property, art. 27, Jan.1,1995

<sup>22</sup> *Supra*



based on existing properties and characteristics of diverse plants.<sup>23</sup> Thus the boundary between product of nature and product of mind<sup>24</sup> is blurred in case of medicinal plants.

Further indigenous knowledge including of medicinal plants is an ancient heritage, continues overtime that is passed on or communicated over a continuous period of time, thus it is not novel though based on innovation hence it does not satisfy the criteria of patents as listed in Article 27. Under paragraphs 2 and 3 Article provides exceptions to general rules in regards to patentable matter.

First exception is on the ground of protecting public order or morality that includes for protecting animal plant, or human and their life or their health. However, when it comes to interpreting of the concept morality public order varies significantly due to different national outcomes. Secondly under paragraph 3 exceptions are laid from patenting of plants, animals, and biological process undertaken for their production. While looking at this paragraph we may find that it gives the developing countries some leeway. However the paragraph also requires the member countries to grant protection to them either through patentability or where there it cannot be so then through sui generis system of protection. Thus members of WTO in the end are either in name of patent or in the name of sui generis system, are not allowed to exclude from, any form IPR protection on the plants and animals. Thus this provision exposes threat of patenting of plants having medicinal properties by the biopirates.

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<sup>23</sup> Vandana Shiva, *The plunder of nature and knowledge Biopiracy*, xvii (Natraj Publishers, 2012)

<sup>24</sup> *Supra*

For purpose of establishing a sui generis system, it is important to know about what constitutes plant variety. However there is no definition, which accepted internationally describing about the constitution of plant variety. Thus raises debate regarding distinguishing between the non- patentable plant and patentable plant. At last it is left to the legislators of nations to determine the meaning of the term and distinguishing about patentability of plant variety.

### 3.3. Convention on Biological Diversity (CBD)

In Rio Earth summit of 1992, the Convention on Biological diversity was drafted, which acame into affect in 1993. CBD is the multilateral treaty regime, which acts as an instrument preventing the loss of biodiversity across the world. Thus focussing on preservation of biological resources of the planet. There were 191 states that were parties to the CBD; this excludes USA from the list as per September 2008. Though USA became signatory to the convention, however it was never ratified by the Senate. It is stated that there exists heavy lobbying of interest groups, who hold different views when it comes to ratification of Convention.<sup>25</sup> The importance of objectives of CBD in regards to protection of biological resources and recognition of indigenou people and their knowledge was realised. Thus provided for measure like benefit sharing to be adopted as one of the objectives of the CBD, that would facilitate recognition and conservation of biological resource and related knowledge. In its sixth meeting in 2006

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<sup>25</sup> Daniel F. Robinson, *Confronting Biopiracy*, 26(Earthscan, 2010).

with regards to benefit sharing, the Conference of Parties to the CBD, adopted the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization.<sup>26</sup> These guidelines provided for development of administrative, legislative or policy measures on access and benefit sharing.<sup>27</sup> Articles 8(j) and 15 of the convention contains the legal principles and criteria for trade of biological resources. This involves the use of natural ingredient that is native to particular place or country and TK associated with that ingredient. The objectives of the CBD include the sustainable use of components of biological diversity, conservation of biological diversity and access to genetic resources along with fair and equitable sharing of benefits arising from utilization of genetic or biological resource.<sup>28</sup>

Article 8(j) of the convention requires parties to the convention to preserve, respect and maintain knowledge, practices and innovations of indigenous as well as local communities that include incorporating and accepting their lifestyles that can be relevant in sustainable use and conservation of the biological diversity.<sup>29</sup> This can be widely possible through involving and getting approval from the holders of such knowledge, practices and innovations. Thus it will also encourage the equitable sharing of the benefits arising from the utilization of such knowledge and practices.<sup>30</sup> Thus Article 8(j) recognizes the rights of indigenous and local communities on their practices, knowledge and innovations, irrespective of whether they are protected by the IPR or not. Further the parties are bound by the Convention to several of important principles

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<sup>26</sup> *Supra*

<sup>27</sup> R.D. Singh, S.K. Patel, H.B. Patel, et.al, *Pharmaceutical biopiracy and protection of traditional knowledge*, 3(2) Int. J. Res. Dev. L. Sci. 868(2014).

<sup>28</sup> UN Convention on Biological Diversity, art 1, June 5,1992, UNEP

<sup>29</sup> UN Convention on Biological Diversity, art 8, June 5,1992, UNEP

<sup>30</sup> *Supra*

concerning biodiversity.<sup>31</sup> Article 15 affirms sovereignty of states over its natural resources. Hence by virtue of these Articles, the states have right of determining their own access regulations to biological resources. In CBD one of the important issue is of Access and Benefit Sharing, which is incorporated under article 15 of CBD that requires national government to formulate their own laws and policies for allowing access to genetic resources. Further this article also requires that for getting access to genetic resources, there shall be shall be a prior consent obtained from contracting states , who are providing such resources. The Government of member state are also required to determine the conditions for restriction on utilisation of genetic resources as well as for access and benefit- sharing. These conditions are to be stipulated in the national laws of member states. In addition to it these conditions and terms that mutually agreed by the parties should be subject to the provisions of CBD. The protection of traditional knowledge and biological resources involves lots of challenges. This may be due to the geographical distribution of large portion of biodiversity of world into tropics. Hence developing countries, having rich biodiversity have formed negotiating group who are negotiating towards inhibition biopiracy. At the same time some of the countries are allowing least control on access of biological resources on which TK exists. They do this in hope of getting various benefits to society and their economies.<sup>32</sup> In CBD, there are provision that have established working groups to resolve some issues like this, however there are more issues like this that are complex and sensitive and are difficult

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<sup>31</sup> Daniel F. Robinson, *Confronting Biopiracy*, 27(Earthscan, 2010).

<sup>32</sup> Daniel F. Robinson, *Confronting Biopiracy*, 28(Earthscan, 2010).

to resolve that relate to customary protocols concerning indigenous, traditional local groups and their cultural concerns over sacred knowledge.

In regards to implementation of CBD, though it is a binding international convention but it lacks in enforcement mechanism and depends on national governments for its implementation. Thus the implementation of the convention is largely depended on willingness of member states to ratify and work on it. Further the language of convention is sometimes criticized to be ambiguous and open for different interpretations. The convention is also criticized for its inability to take stand against intellectual property rights that threat to biodiversity and of overriding the objectives of the convention, for example in Article 20 priority has been given to social and economic development that includes eradicating poverty in developing countries. Hence in one way it is diverging from its own objectives. Thus due to these lacunas in convention, it stated to be failure when it comes to fulfilling the expectations of both developing and developed countries and still not completely successful to achieve its aim of eradicating evils of biopiracy and protecting TK holders' interest.

### 3.4. Nagoya Protocol

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable sharing of Utilisation to the Convention on Biological Diversity is a supplementary document to CBD.,which was adopted in Nagoya, Japan on 29 October 2010.<sup>33</sup> The protocol came into

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<sup>33</sup> Convention on Biological Diversity, *About Nagoya Protocol*, (last visited July 20,2020), <https://www.cbd.int/abs/about/>

force on 12 October 2014, which was after passing of ninety days from the deposit of the fiftieth instrument of ratification.<sup>34</sup> The protocol was adopted to correct the lacunas of the Convention and covers traditional knowledge along with its main objective of fair and equitable sharing of benefits that arise from the utilisation of genetic resources, thus contributing to sustainable use and conservation of biodiversity.<sup>35</sup> The protocol has been already ratified by India and South Africa and signed by Brazil. It has stronger binding commitments of nations in respect of ABS issue, which the CBD lacked, but is also claimed as a successful enactment that provides the developing countries and indigenous communities protection from the claims of biopiracy.

The preamble of the protocol besides highlighting its objective of fulfilling the objectives of CBD also states about problems faced in implementation of CBD. Under Article 5 it is stated that the objectives should be attained by mutually agreed terms and conditions between the parties to the protocol and shall take up measures through enacting laws and policy and through administrative directions. Article 7 of the protocol mandates that prior approval or consent of the indigenous communities has to be taken for accessing traditional knowledge held by them and assigns state with responsibility to ensure adequate measures have been taken by it as per their domestic laws for the same. Further, mutually agreed terms and conditions should be decided by the parties. The protocol includes its scope chemicals extracted from the biological sources based on which medicines or drugs are made.

Under Article 15 and 16 requires each member to comply with the domestic laws of respective member state for accessing and benefit-sharing genetic resources and traditional

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<sup>34</sup> *Supra*

<sup>35</sup> *Supra*

knowledge respectively. These compliances are mandatory for both the user and provider state of such resource or knowledge. Under Article 18 the members while contracting with each other through mutually agreed terms must include provision regarding dispute resolution. Thus making clear that benefit sharing and accessing is a contractual, which can be enforced through justice system. The Nagoya Protocol provides for elaborate set of rules concerning mutually agreed terms, access procedure and prior informed consent.<sup>36</sup> However it does not provide for much scope of improvement for the local and indigenous communities' rights on their knowledge and resource, even though it stipulates that such communities have rights over the traditional knowledge they possess and right over the genetic resources that are located in their territory. Despite giving recognition of rights of indigenous community, the protocol does not define these rights. The Nagoya protocol provides for adoption of dual prior informed consent its principle, which means that consent of both national authorities and indigenous communities has to be obtained by informing and obtaining consent from them before accessing genetic resources or TK is put to use. The protocol does have some defects that are; the protocol does not enumerate upon access to drugs made through resources or TK and compensation for indigenous people in case of violation. It does not deal with biodiversity management planning or with the implementation of the same. The protocol is largely dependent on states for its implementation. Though the protocol suffers from lacunas but it has clarified some unresolved issues under CBD. Hence, when in regards to its success or failure it is dependent on initiatives of the member state, who may or may not adhere to the provisions of the protocol completely.

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<sup>36</sup> *Supra*

Besides this landmark convention and protocol there have been earlier attempts made for purpose of protecting and giving recognition of TK to indigenous people. These include United Nations Draft Declaration on Rights of Indigenous People in 1994, where under Article 29 of the Declaration the ownership rights of TK by indigenous communities was recognised. The Article mandated protection, control and ownership of culture and intellectual property of these communities. This includes to manage and protection of humans, seeds, oral traditions, genetic resources, medicines, literature, knowledge pertaining to flora and fauna, designs, visual and performing arts. The Indigenous and Tribal Peoples Convention of 1989 recognised rights of indigenous and tribal people over natural resources and specified safeguarding of their land. The rights include participation of these people in management, conservation and use of resources under Article 15(1) of the Convention. The Convention also recognised people's aspiration to control and maintain their own institutions, development of their social and economic identities that included their religion and language within their State's framework. Further International Labour Organisation emphasised on recognising indigenous people's right.



## Chapter 4: ACCESS AND BENEFIT SHARING AND BIOPIRACY

Biopiracy is an outcome unauthorised use or misappropriation of the genetic/ biological resources or their TK through use of Intellectual Property Rights, without giving recognition or accruing benefits to the provider of those genetic resources or TK relating to genetic resources. This phenomenon is major cause of concern by developing countries, who often face issues like loss of revenue, depletion or extinction of specific specie or biological resource, cultural and identity loss of the indigenous community, who are owners of TK. Hence biopiracy causes unequal development between the developing and developed nations. Countries like India, Mexico, South Africa and Brazil etc. often become victim of biopiracy by industrialised countries like the UK, USA like observed in the biopiracy cases of Neem from India and Hoodia Plant from South Africa. As mentioned earlier CBD through Bonn guidelines provides for Fair and Equitable sharing of benefits that arise through utilisation of genetic resources, which further evolved in the Nagoya Protocol by establishing the access and benefit sharing (ABS) regime. These enactments were adopted for purpose ensuring conservation and sustainable use of biological resources, however eradication of biopiracy is one of the implicit objective of these enactments through ABS regime that was duly recognised as one way of combating biopiracy by the developing nations. Thus helping in keeping a check on unauthorised use of biological resource and associated TK.

4.1. Access and Benefit Sharing: It is a way by which the genetic/biological resources and knowledge related to it can be assessed by the users of the

resource by sharing benefits resulting use of such resource or knowledge with the provider of the same. These users and providers may person or countries.

4.1.1. Importance: ABS ensures that the providers of the biological resource or TK holders are ensured with benefits that arise due to the use of biological resource or by TK. This benefit can be in form of monetary terms such as royalties, which may arise from research activities or commercial products that may be developed by use of such resource or knowledge. It can also be in non -monetary form such as fostering research and development skills or transfer of technology etc. ABS further ensures that users are able to physically access the biological resources and benefits that accrue from them are shared in fair and equitable manner with the providers. Thus it is required that both users and providers respect the institutional and legal framework as stated in the CBD and Nagoya Protocol.<sup>37</sup>

4.1.2. Working: In ABS the user is required to obtain prior informed consent (PIC) from the provider, where both the user and the providers negotiate on mutually agreed terms in accordance with the national policies and institutional framework of the resource provider country. Grant to access genetic resources may be provided by provider country through either from seed banks or other ex-situ conservation facility. Further the parties are required to establish Access and Benefit Sharing

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<sup>37</sup> Convention on Biological Diversity: ABS, *Introduction to access and benefit sharing*, (last visited July 27,2020), <https://www.cbd.int/abs/infokit/revised/web/all-files-en.pdf>.

Clearing House (ABSCH) as stated in Article 14 of the Nagoya Protocol. This clearing house serves as a platform for facilitating information exchange. It also used by parties, businesses, non- parties and local as well as indigenous communities to share information relating procedure and regulations for access of biological resources and TK. Further helping countries to monitor utilisation of biological resources and raise awareness relating to same.

#### 4.1.3. Case study: Benefit Sharing arrangement with Kerala's Kani Tribe of India.

This case is an example of benefit sharing arrangement entered between Tropical Botanical Garden and Research Institute (TBGRI) and tribal community of Kerala called Kani. This tribe used a fruit of plant called Arogyapaacha for vitality and instant energy. Knowledge of it was given to TBGRI, a research institute of Trivandrum, by three member of this tribal community, while on expedition to the forest, where the tribe inhabited. Later after scientific experiment the scientist of TBGRI developed a drug called jeevani using this plant added with ingredients from other medicinal plants. Accordingly the director and governing body of TBGRI gave a right of manufacturing drug jeevani to Arya Vaidya Pharmacy Ltd , a commercial firm for period of seven years on payment of licence fee around US \$ 30,000.<sup>38</sup> TBGRI was entitled to receive two percentage of future sale of drug as royalties and CSIR guidelines Kani tribe were entitled to 50 percentage of licence fee and 50 percentage of royalties received by TBGRI. A trust called Kani Samudya Kshema Trust was registered in 1997 and first

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<sup>38</sup> Biswajit Dhar & R. V. Anuradha, *Access Benefit-Sharing and Intellectual Property Rights*, 7 J. World Intell. Prop. 631 (2004).

payment of royalties and licence fee was handed to the trust in 1999. Further special incentive was given to the information providers to TBGRI. However this arrangement was not free from problems that included absence of consultation of Kani tribes, who lived in other areas, which as per TBGRI's view there was no legal requirement pertaining to the same and they were not made aware any customary requirement for seeking permission from Kani medicinal practitioners before use of the plant.<sup>39</sup> Further it was found that compensation awarded to the Tribe was not adequate for sharing their knowledge.

Thus example highlighted two major problems of access and benefit sharing arrangement that as per CBD the arrangement between the parties must be voluntary. However in this case where segment of tribe was not adequately represented and benefits accrued were confined to the tribe located a particular place. Hence the question remains is whether such arrangement entered fulfils the objective of fair and equitable benefit sharing. Further the second problem of inadequate compensation to tribe. Thus here, it can be said that attempt of providing fair and equal benefit sharing was half made.

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<sup>39</sup> *Id.* at 632

## CHAPTER 5: MEASURES TAKEN BY INDIA

India is one of those countries that have rich biodiversity. The country has adopted several laws that are concerned with protection and conservation of biological resources. The Constitution of India under Article 21 attributes environment and biological resources a fundamental right status, which is necessary for life and livelihood of an individual. Further the 42<sup>nd</sup> amendment to the constitution inserted Articles 48 A and 51-A (g) that imposed obligation on the state to protect natural environment and similarly on citizen under Article 51-A (g) that elaborates fundamental duties of citizen. Further the country has also established specialised legislations that are concerned with resource conservation this includes forests and forest produce, plant varieties etc. However, the country did not have any specific legislation that would deal with problem of biopiracy unless enactment of Biodiversity Act, 2000 that lay emphasis on access to benefit sharing as measure to curb biopiracy.

### 5.1.Challenges Faced by India

India is seventeen mega-biodiversity countries that has 2.4 per cent of the global land area.<sup>40</sup> It accounts to have seven to eight per cent of spices recorded of the world, thus making it more prone to biopiracy.<sup>41</sup> India observed a series of cases where it had revoked the patents on healing properties of plants and herbs after the landmark judgment relating

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<sup>40</sup> R.D. Singh, S.K Mody, H.B. Patel, et.al, *Pharmaceutical Biopiracy and Protection of Traditional knowledge*, 3(2), Int. J. Res. Dev. Pharma. L. Sci., 869 (2014)

<sup>41</sup> R.D. Singh, S.K Mody, H.B. Patel, et.al, *Pharmaceutical Biopiracy and Protection of Traditional knowledge*, 3(2), Int. J. Res. Dev. Pharma. L. Sci., 869 (2014)

to patenting of Turmeric. These cases included the patenting of neem, Indian ginseng etc. These cases are instances of challenges that India had faced or is facing. Besides India other developing countries like Bolivia, Ecuador, Peru, Thailand, Cuba, Brazil etc. had been fighting against WTO against Biopiracy. These countries had emphasised that in the TRIPS Agreement should recognise the rights of indigenous people, who are the holders of traditional knowledge and should share benefits that arise out of innovations made through use of biological resources and knowledge. They advocated for refusal of granting patents on life forms and also stressed up on harmonisation of TRIPS provisions with those of CBD, since CBD lacked the implementing machinery or force. Further they recognised that in the absence of mutually supportive relationship in TRIPS, that was provided as member obligation under CBD, to combat biopiracy<sup>42</sup>. Thus they demand for amending in the TRIPS Agreement to provide for provision regarding disclosing source and origin country of the biological resources and TK incorporated used in invention, giving evidence supporting the prior consent from concerned authorities obtained as per the national regime and providing evidence for fair and equitable benefit sharing as per the national regime of the origin country . However opposition in regards to amending TRIPS Agreement were shown by countries like USA.

Further it was argued that these disclosure requirements had already been incorporated by several countries in their respective national legislations against the contention placed by the USA that patent system had continued to serve as effective tool for ecological and economic development and the said amendments may not be successful in fulfilling objectives desired. Further it was stated that the said amendments would prove to be

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<sup>42</sup> Kasturi Das, *Combating Biopiracy*, (last visited June 24, 2020), <http://indiatogether.org/biopiracy-environment>.

detrimental to the patent system. India and other countries contended that biopiracy was a global problem, thus measures to be undertaken by member state, were depended on the state for their implementation and the ones that, are incorporated at national level only would not be sufficient to tackle with problem of biopiracy. Thus by incorporating them into TRIPS, which was duly adopted by most of the nations, would act as ideal means to curb this problem.

Besides these proposals being placed in the council, India and like-minded countries had also taken another significant that Council of members in WTO. This involved submitting of Checklist of issues. The purpose behind submission of check issues was to provide result oriented questions on the subject that are aptly structured. While most of the countries agreed that this method was a good basis for further deliberations in the council, USA along with Japan supposed opposed Post check list approach stating that WIPO would serve as a better forum for detailed discussions on such issues.

These deliberations still continues to exists, while the India and other countries continue to make proposals to attain the intended objectives, though methods of doing so may not be the same.

Despite, the deliberations made at international level to curb biopiracy not make permanent mark. India based on the provisions of CBD and effectively incorporating Nagoya protocol enacted Biodiversity Act, 2000 and formulated Traditional Knowledge Database Library in order to keep check on the problem of biopiracy.

5.2.Biodiversity Act, 2000: India, being a contracting party to CBD had enacted the Biodiversity Act, 2000 in the line of the provisions of the

CBD as enforced in the Nagoya Protocol. This enactment was an attempt to address concerns relating to access to collection and utilisation of biological resources and TK by the foreign nationals including sharing of benefits arising out of such access.<sup>43</sup> Thus main objective of the Act is conservation of biodiversity and prevent misappropriation or biopiracy of biodiversity and knowledge related to the same. The Act prescribes for the establishment of National Board of Approval (NBA) and State Biodiversity Board (SBB). Under section 3 of the Act makes provision for prior consent of the NBA for certain persons for obtaining any biological resource or knowledge relating to such resource for research or commercial utilisation, thus also include knowledge about medicinal properties of plant. Section 4 debars any person to share research results or knowledge relating to biological resource obtained from India with person not citizen of India or not a resident of India. Under section 7, prior intimation to the State Board is required to be given for commercial utilisation or bio survey of biological resources by person that includes individual, body corporate or organisation of Indian citizenship or nationality. Section 8 of the Act requires the NBA to have a member from the Ministry dealing with Indian systems of Medicine and Homoeopathy. Under the following Act there provisions enacted for protection of traditional knowledge. In order to ensure equitable sharing of benefits derived from the biological

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<sup>43</sup> Kasturi Das, *Combating Biopiracy*, (last visited June 24, 2020), <http://indiatogether.org/biopiracy-environment>.



resources and knowledge reacting to them, section 19 and 21 stipulate for the prior approval by the National biodiversity Authority (NBA) before accessing them. Section 6 requires that anybody who wants to seek any intellectual property right on any research that is based upon biological resource or knowledge obtained from India. Then prior approval for the same is required to be obtained by the NBA. Further the NBA is empowered to impose benefit sharing conditions benefit sharing fees or royalty or both. Under section 18(4) of the Act one of the function of the NBA is to take measures to oppose granting of Intellectual Property Rights (IPR) to any country outside India on any biological resource obtained from India or knowledge associated with such biological resource derived from India. Further the Act provide for penalties to be imposed on infringement of section 3, section 4 and section 6 under Section 55(1). The penalty section provides for five years of imprisonment or fine extending to ten lakh rupees. Besides these provisions the Act seeks to do other tasks such as regulating biological resources with purpose of securing sharing of equitable benefits arising from the use of biological resources and associated Traditional Knowledge (TK) including conservation and sustainable utilization of biological diversity.

The Biological Diversity 2002 is one the significant step taken by India, however one of the major problem that is posed by the Act, in regards to involvement of

communities, who are owners of TK. CBD and Nagoya Protocol recognised right of the indigenous resource or TK holders through prior consent to be obtained before utilisation or appropriation of biological resource or associated TK. Accordingly the Act contains provisions pertaining prior consent from the concerned governments, who act as representatives. However it is argued that communities' interest in regards to exercising their control over resources and TK may not coincide with the interests of the government. Hence demand of fairness and equity of the TK holders cannot be substituted by the government agency. Problem that these indigenous or local communities face include lack recognition of rights over land, where these communities reside; disintegration of local communities into segments, thus difficulty in ascertaining the TK holder or as custodians of biological resource; conflicts between traditional communities and non traditional or with political powers. Thus such cases there may be disparities when it comes to involvement of such communities, whose interest may possibly been ignored or not adequately represented.

#### Biodiversity Rules 2004

Besides the Biodiversity Act, 2002, the biodiversity rules were enacted which came into force on April 15, 2004. The rules were framed in the exercise of the power conferred under the section 62 of the Act. Under rule 12, which enumerates the general functions of the authority sub rule xiii states about the function of the authority to take steps to create a data base, information and documentation system for biological resources and associated traditional knowledge either in the form of registers electronic databases so as to ensure effective management promotion and sustainable use of biological resources

and knowledge. In sub rule xix it is required for authorities to take measures for appointing legal experts in order to oppose intellectual property right granted on any biological resource and associated knowledge in any foreign country that is obtained in an illegal manner. Rule 14 lays down procedure for access to biological resources and associated traditional knowledge.<sup>44</sup>

5.3.Traditional Knowledge Digital Library (TKDL): One of the measures taken by the Indian Government against the biopiracy of medicinal plant was the creation of the Traditional Knowledge Digital Library. This project is collaboration between Council of Scientific and Industrial Research (CISR), Ministry of Science Technology and the Department of Ayurveda, Yoga and Naturopathy, Unani, siddha and Homeopathy (AYUSH), Ministry of Health and Family Welfare. This digital library was created for the purpose of documenting of traditional knowledge from existing literature like Ayurveda, Unani and Siddha in digitalized format to make available in the public domain. The documentation was done five languages that are English, German, French, Japanese and Spanish. The purpose behind was to provide access of this database to International Patent Offices in order avoid granting of wrongful patents on traditional knowledge including the patents granted on the medicinal properties of herbs. The TKDL includes about 2.12 lakh medicinal formulations 82,900 from Ayurveda; 1,15,300 fro Unani; 12,950 from

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<sup>44</sup> Ministry of Environment and Forest, Biodiversity Rules, 2004, (last visited June 27,2020), <http://nbaindia.org/uploaded/Biodiversityindia/Legal/33.%20Biological%20Diversity%20Rules,%202004.pdf>.

Siddha, documented from 148 books available in public domain, and the databases. The Government of India has given approval to International Patent Offices, for accessing TKDL through Non-disclosure Agreement, between respective International Patent Office and CSIR, as per which: -

5.3.1 Access to TKDL would be given to examiners of these international patent offices that can used only for patent examination and search, and

5.3.2 Examiners and International Patent Offices cannot make any third party disclosure, that excludes information, which is necessary as well as essential for search and examination of patents.

European Patent Office (having 35 states), German Patent Office, United States Patent and Trademark Office besides Indian Patent Office are some of the patent offices have been given access to TKDL.<sup>45</sup>

TKRC

Indian introduced Traditional Knowledge Resource Classification (TKRC) system, which played an important tool in digitalizing the Sanskrit text of Ayurveda and other ancient language to other languages, in which TKDL can be access into. TKRC is formed on classification system that is structured and is modelled on WIPO's International Patent

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<sup>45</sup> Council of Scientific and Industrial Research, Traditional Knowledge Digital Library, (last visited June 24, 2020), <http://www.tkd.l.res.in/tkd/l/angdefault/common/Abouttkdl>.

Classification (IPC)<sup>46</sup>. The TKRC contains about 27,000 subgroups for Ayurveda, Siddha, Unani and Yoga similar like IPC. This makes it indispensable and easier for retrieving relevant information.<sup>47</sup> This system prompts for IPC's reformation as an important tool that will facilitate search and examination of application of patents that are related to TK with efficiency. The IPC is divided into eight sections having approximately 70,000 subdivisions. These subdivisions are assigned a symbol that consists of Arabic numerals and letters of the Latin alphabet.<sup>48</sup> There was only one subgroup for medicinal plants that existed until 2005. This meant that patent examiners did not have sufficient information or mechanism through which they could examine patent applications that were based on traditional medicine.<sup>49</sup>

India identified this lacunae of absence of sufficient recognition of traditional medicines in the expert committee of IPC that led to the establishment of Traditional Knowledge Classification Task Force. The Traditional Knowledge Classification Task Force comprised of five member groups, which included the European Union, China, Japan India and the United States. Thus, there was increase in the number of total sub groups from 1 to 207 that were related to medicinal plants. This brought far-reaching reforms and fundamental changes in the International Patent system.

### Impact of TKDL on biopiracy

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<sup>46</sup> World Intellectual Property Rights, Protecting India's Traditional knowledge, (last visited July 20, 2020), [http://www.wipo.int/wipo\\_magazine/en/2011/03/article\\_0002.html](http://www.wipo.int/wipo_magazine/en/2011/03/article_0002.html)

<sup>47</sup> World Intellectual Property Rights, Protecting India's Traditional knowledge, (last visited July 20, 2020), [http://www.wipo.int/wipo\\_magazine/en/2011/03/article\\_0002.html](http://www.wipo.int/wipo_magazine/en/2011/03/article_0002.html)

<sup>48</sup> *Supra*.

<sup>49</sup> *Supra*

TKDL was one of the significant steps taken by India, which helped India in fighting biopiracy case on the medicinal plants. European Patent Office is one such body where the impact of the TKDL was felt. Since July 2009, EPO's TKDL team has identified 215 patent applications relates to Indian medicinal systems for which TKDL evidences were filed as a third party<sup>50</sup>. In two of such cases the EPO has relied in data from TKDL as evidence and has reversed or revoked its intention of granting patents. Thus the TKDL has proved to be an effective deterrent against biopiracy.<sup>51</sup> Biopiracy of genetic resources and misappropriation of TK have become a growing concern of many countries including their local and indigenous communities. Even though issues like this have been raised in various multilateral forums like the Convention on Biological Diversity (CBD), the World Intellectual Property Organization (WIPO), and the TRIPS council of the World Trade Organisation, yet a framework to that is accepted globally for protection of TK is not established.<sup>52</sup>

India is the only country in the world that has established TKDL. Its is a mechanism through which it can protect its TK. It facilitates comparatively prompt, effective and involves less or fewer cost in revocation of applications for patents, that relate to TK of India. In sharp contrast, in absence of TKDL, it took almost more than six years for revoking the patent granted on neem for its antifungal properties<sup>53</sup>. Thus TKD created a possibility in terms of revocation of wrongful patents granted on TK of India.

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<sup>50</sup> *Supra*

<sup>51</sup> *Supra*

<sup>52</sup> *Supra*

<sup>53</sup> *Supra*

Besides the above-mentioned measures, India recognising the provisions of CBD amended its Patent Act, 1970 in year 2002, which added two additional grounds for revocation of patents that includes incomplete or non disclosure of the biological material put to use in invention and when invention amounts to be a claim or anticipated relating to knowledge or oral, traditions of any indigenous or local community within India or outside India.

## CHAPTER 6: BIOPIRACY AND JUDICIAL CASES

### 6.1.Turmeric

Introduction: Turmeric (*Curcuma Longa* Linn.) is native plant form Southern Asia including India, belonging to ginger family. The plant is usually gathered for their rhizomes, which are then converted into powdered form. Besides used as culinary ingredient, having cosmetic application and dyes it has several medicinal properties as stated in the Ayurveda, Siddha that include its ability to heal wounds, body ulcer, and rashes and had ability to be used in fighting cancer.

Facts: In 1995, Hari Har P. Cohly and Suman K. Das, two Indians from University of Mississippi Medical Centre were granted a patent, that was number as 5, 401,504 an USA patent for use of turmeric to heal wounds. The patent was challenged at USPTO with request re-examination of case by Council of Scientific & Industrial Research (CSIR), India, located at New Delhi on ground that healing properties of turmeric was already been aware and was made used by Indian people since long age. Thus it would fall in the category of prior art, hence making the patent claimed obvious in nature.

Claims and contentions: It was claimed by the applicants that turmeric had ability to treat wound including surgical wounds and body ulcers, whereas it was argued by CSIR that turmeric was being used since thousand years for healing rashes and wounds. Hence medical use of turmeric does not satisfy the invention to be novel, this claim of



CSIR relied on Sanskrit text along with paper in Journal of Medical Association published in 1953 as the documentary evidence of traditional knowledge.

Impact: Relying on contentions and upholding the documents presented by the CSIR, United States Patent and Trademark Office (USPTO), after ascertaining that there was no novelty as the findings of innovators involved nothing new and the same already existed in India for centuries. Thus it revoked the patent in 1997.

Conclusion: the case was landmark judgment that illustrated the weakness in the US patent law, which facilitated biopiracy; one of them is the interpretation of the term 'prior art'.

## 6.2.Neem case

Introduction: Neem also known as Indian lilac (*Azadirachta Indica*) is native plant of India and is also found in countries like Nepal, Pakistan, Bangladesh and Sri Lanka. The trees is said to possess medicinal properties, which include being anthelmintic, antifungal, anti diabetic, antibacterial, antiviral. It is considered be an important component of Siddha, Unani and Ayurvedic medicine and especially prescribed for treating skin diseases, improving liver functions, detoxification of blood and balancing bold sugar levels. Besides it also acts as natural insect repellent.

Facts: In the year 1990, USA's multinational chemical company called W.R. Grace and Company, and the United States Department of Agriculture filed a European Patent Application for a fungicide derived from the neem extracts, which was granted after a long examination procedure in year 1994. W.R. Grace transferred the patent obtained to Thermo

Trilogy, its former affiliate in 1996. This patent granted was challenged by three people, that included New Delhi's Research Foundation for Science, Technology and Ecology's director Vandana Shiva; vice-president of the International Foundation of Organic Agriculture Movements (IFOAM), Linda Bullard; and European Parliament's Green Group president Magda Aelvoet.<sup>54</sup> The patent challenged was the part of Neem Campaign of India that was launched by Indian farmers in the year 1993; they feared that the patent protection given would increase foreign control over their resources in TK.

Contention and claims: The opponents made a claim of invalidity on the grounds under Article 53(a) of the European Patent Convention. Paragraph (a) that contains exception to grant of patent, on ground that invention is contravention of morality and public order.<sup>55</sup> Further the opponents contended that patent would threaten the livelihood of millions of neem tree gatherers since neem tree seeds will be exported in large quantities for purpose of producing fungicide, hence this will lead to exhaustion of natural resources. If the company starts growing a natural product only for itself, then supply of resource will become restricted.<sup>56</sup> Secondly, if this patent would be granted then Indian people right over their natural resource and cultural heritage would be deprived. Hence by denying its existence as constituting prior art would amount to violation of rights of these people, and the community would be denied its right to use this natural resource and traditional knowledge pertaining to it, who own a rightful claim over it.<sup>57</sup>

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<sup>54</sup> Vandana Shiva, *Controversy over Biopiracy and Developing World*, Organic Consumer Association, (Mar. 16, 2007), <https://www.organicconsumers.org/news/vandana-shiva-controversy-over-biopiracy-india-developing-world>.

<sup>55</sup> *Supra*

<sup>56</sup> *Supra*

<sup>57</sup> *Supra*

Judgment: The opposition against patent was made on the grounds that it lacked novelty, there was lack of inventive step, disclosures made were insufficient and it was contrary to morality. The European Patent Office (EPO) decided to revoke patent on anti-fungal properties neem seed for producing fungicide in 2000. The arguments on the basis of which the EPO made its decision was by relying on article by H.B. Singh and U.P. Singh published in 1980 named as 'Effect of Volatiles of Some Plant Extracts and their Oils on Conidia of Erysiphe Polygoni DC'.<sup>58</sup>. Based on documents relied it was stated that invention did not fulfil the prior art condition as it obvious by the fact knowledge in regards properties of neem was already used in India.

Thus turmeric and neem were the landmark judgments in respect to biopiracy of medicinal herbs in India, thus after these judgment, the Indian Government took initiative to a digital library in regard to traditional knowledge of plants and herbs in the form of Traditional Knowledge Digital Library

### 6.3.Indian Ginseng case

Introduction: Indian Ginseng commonly known as Ashwagandha (*Withania Somnifera*) is used as herb in Ayurvedic medicine

Facts: In May 2001, American and Japanese firms filed applications for the issue of patent, which favoured them on invention that had formulations or extracts of *Ashwagandha*. Pola Chem Tech., a firm from Japan, made the patent application. This

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<sup>58</sup> *Supra*

patent was for developing a topical skin ointment to be used for cosmetic purpose and to promote fertility. On the other hand New England Deaconess Hospital of USA had successfully been granted patent on alleviation of symptoms of arthritis by use of Ashwagandha. On 27 July, America's multinational company called Natreon Inc. filed an application for patent in the EPO. The patent was filed on long use of *Ashwagandha* to treat insomnia, anxiety induced stress, gastric ulcers and depression. India was successful in revoking one of the several patents that granted on medicinal properties of Ashwagandha. Indian authorities submitted evidences from Traditional Knowledge Digital along with some documents from 12<sup>th</sup> century on 6 July 2009. These sources were relied as India's reply to crush an attempt made for getting patent. Ashwagandha is recognised as diuretics, aphrodisiac and for treating and restore memory loss problem in Ayurvedic system of medicines.

Judgment: American firm's claim over Indian Ginseng was decided to be dismissed by EPO and hence revoking the patent on March 25, 2010 on grounds that it did not fulfil the non-obvious criteria as knowledge pertaining to its medicinal properties could be traced in TKDL.

#### 6.4.Jamun

Introduction: Jamun (*syzygium cumini*) is an evergreen tropical tree, which is native to Indian Subcontinent, is known for control diabetes and cure for digestive ailments.

Facts: A drug maker company Avesthagen, which had head quarter at Bangalore was granted patent by Indian Patent Office for a medicine made from the extracts of Jamun, lavanpatti and Sandalwood. The Department of Industrial Policy and Promotion in the Union Government Ministry (government) challenged the same using the rare provision in the Patent Act. The company presented argued that patent was novel and not prejudicial because it was a scientific validation of Indian traditional knowledge. However, the government viewed that validating something that is already a part of traditional knowledge cannot be ground for granting patent.

Judgment: the patent was revoked in the year 2012 on the grounds that the patent right was detrimental to the state and genera prejudicial to the public. The medicinal properties of Jamun were already part of Indian medicine system of Ayurveda, Unani and Siddha.

#### 6.5.Colgate- Palmolive case

Introduction: The Colgate- Palmolive is an American company that deals with consumer products. The company focuses on production, distribution of health care and personal products such as soaps, toothpastes, toothbrushes etc.

Facts: Colgate-Palmolive, a company from New York had filed a patent claim at European Patent for composition that contained botanical extracts from 3 herbs that included cinnamon, also known as dalchini. Further, two years from the date when first patent claim was filed, the company filed for another application in 2010 to EPO, to seek protection for oral composition, other then the previous one. This composition contained ginger, components of Bakul tree, nutmeg, camphor, cinnamon, components

of Indian banyan tree, turmeric, black pepper, neem, clove and long pepper for a solution for treatment of oral cavity. Both patents were challenged by India in European Patent Office with the support of Traditional Knowledge Digital Library (TKDL).

Judgment: The first application was challenged and European Patent Office ruled in India's favour on May 2011, The second application was challenge on June 2014 and the patent was rejected on basis of Traditional Knowledge Digital Library, which proved to patent examiner that patent claims of Colgate were not novel. The composition contained the extracts from the plants or herbs from the ancient Indian texts for treating the same disorders as claimed by the Colgate.

The above cases demonstrate India success against its measure to curb biopiracy of its medicinal plants. India's initiative of establishing TKDL later proved to be successful, when it comes to revoking patents granted like in cases of Indian Ginseng and Colgate –Palmolive case.

#### 6.6.Divya Pharmacy v. Union of India <sup>59</sup>

The case relates to the interpretation of Biodiversity Act, 2002, which was enacted by India after adopting CBD and the Nagoya Protocol.

Facts: Divya Yog Mandir, trust founded by Swami Ramdev and Acharya Balkrishna engaged in production of Ayurvedic products through its commercial unit Divya Pharmacy. These products use biological resource as a key ingredient and raw material. The petitioner i.e. Divya Pharmacy were sent notice by Uttarakhand Biodiversity Board to make payment under Fair and Equitable Benefit Sharing (FEBS) of Biodiversity Act,

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<sup>59</sup> Divya Pharmacy vs. Union of India and Others, Writ petition (M/S) No. 3437 of 2016

2002 along with its rules. The petitioner challenged the same in the Uttarakhand High Court.

Issues:

- 6.6.1. Whether the State Biodiversity Board (Uttarakhand) power impose fee under Fair and Equitable Benefit Sharing to an Indian entity/ person?
- 6.6.2. Whether State Biodiversity Board have delegated power of National Biodiversity Authority of imposing FEBS on entity/ person falling under Section 7 of the Biodiversity Act?

Contentions: The petitioners contended that the State Board could not demand payment under fair and equitable benefit sharing since, by doing so it would exceed its jurisdiction. Further relying on sections 3, 7, 2(g) and 21 of the Act, the petitioners are not liable to pay an amount under FEBS. Where as respondents argued that FEBS did not distinct between foreign and Indian entity, further such distinction if made would be against the purpose of the Act and against the international convention and protocol to which India is signatory.<sup>60</sup> Relying on sections 2(g), 7, 23 and 24 the State Board was empowered to regulate activity in regards to utilisation and protection of biological resource.

Held: The court in this case recognised the objective of the Act as well as of the CBD and protocol, which was to protect the interests of local and indigenous communities in regards to protection of their TK and community rights of over biological resource and its TK. Further relying on sections 2(g)16, 18 and 21 of the

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<sup>60</sup> *Supra*

Act, the court recognised the powers of NBA to formulate regulations in respect to ABS and FEBS so as to provide due non- monetary or monetary benefits to these communities of indigenous and local people. It also recognised the role of NBA and SBB to take appropriate measures for biological resource conservation and facilitating benefits to such communities as envisaged by the convention, protocol and the Act. Hence it was held by the court, that state, being a regulator of activities has power to demand fees form the petitioner under FEBS. Owing to the fact that petitioner was using biological resources for commercial activity, the SBB has duties and powers to collect FBS as its regulatory measure under section 7 and 23 of the Act. Thus SBB was empowered to demand payment under FEBS from the petitioner. The court in this case also highlighted about the various terms and percentages of amount, which an applicant entering into access and benefit sharing terms for utilisation of biological resource or for TK has be given to providers.

## CHAPTER 7: CONCLUSION



Biopiracy of Medicinal plants is one aspect of biopiracy at global level, though several attempts are made to curb it at both international level and national level, it will continue to pose problem with rapid development in the field of biotechnology if not dealt with properly. In chapter three of dissertation we observe that though several international agreements, institutions and conventions were formulated and had taken initiatives to curb this problem, there had efforts were found not sufficient enough to deal with this problem. The WIPO despite being important organisation of UN in respect of Intellectual Property Rights was not able formulate a harmonized patent regime which would have binding effect on all nations and would cater interests of all groups of people like it was unable to recognise indigenous people's rights over the resources and knowledge in respect of those resources which these groups had been observing and utilizing since centuries.

The TRIPS agreement that is considered one of best piece of legislation in respect of IPR did not contain provisions like mandatory disclosure requirements as proposed by developing nations, which had potential to curb biopiracy to certain extent. Further the controversial Article 27 was not amended despite criticised by countries for contributing to practice of biopiracy. While CBD had taken significant measures to confront with problem of biopiracy, had lacked enforcement mechanism and had lacuna like not taking firm stand against IPR threatening biodiversity. However attempts were taken to correct the lacunas of CBD in Nagoya protocol, which was again one of the most significant steps to curb the issues related to biopiracy of TK. Access Benefit Sharing and TK holders' rights but again it depended on countries and their national legislation for implementation hence could not be enforced uniformly.

Though India was unable to implement on its deliberations regarding disclosure provision, it had taken significant steps to combat biopiracy at national level, which include enforcement of Biodiversity Act, 2000, which provides for Access Benefit sharing and Conservation of biodiversity, and thereafter establishment of TKDL to keep check on biopiracy incidents in respect of medicinal plants. TKDL has proved to be one the successful initiative to combat biopiracy cases like in Colgate-Palmolive case, thus it grants information regarding medicinal properties of the various plants that were practices and adopted by people of India through centuries protection from becoming a subject of patent. This database have also been recognised in other countries like the European countries, US Patent and Trademark Office etc. Recognising the success of this initiative. An attempt was made in year 2016, where a bill concerning protection of traditional knowledge was introduced in Indian parliament. The bill failed, while looking at the international level, it is required that disclosure requirements as suggested by developing countries in their deliberations to the TRIPS Agreement is implemented. Further there should be common platform or system introduced to look into matters relating to patenting of traditional knowledge and enough considerations should be given in regards to medicinal plants across developing and developed countries. This will also keep a check on resource exploitation of developing nations and will ensure that development parameters that can be attained through Access Benefit Sharing system is balanced and beneficial for both developing and developed nations. Further a Uniform Code at internationally level can be introduced for the purpose of taking strict actions against biopirates. In addition to it other countries that are facing the problem of biopiracy could formulate database like TKDL.

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