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### To Study Patent Laws as a Boon or Curse against Biopiracy

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#### ABSTRACT

Biological resources and the traditional knowledge related to them is a matter of great concern for the indigenous people and their state. The United Nations in its declaration on the rights of indigenous peoples declares collective rights of indigenous people-such as culture, identity, language, access to employment, health, education, and natural resources. The involvement of commercialization throughout the world has evoked the use of biological resources at an alarming rate. The extensive commercialization in the globe has lead to the use of biological resources and the traditional knowledge related to them by various global companies for producing various commercial products. These companies in order to hold the monopoly in the global market, for their products have applied for patents, irrespective of the fact the biological material and the traditional knowledge related to produce the product was acquired by them without any consent from the native state of the biological material. Some of the global companies were even granted patents for such biological resources. However, the patent laws for such global companies acted as a boon, but for the indigenous states to which the biological resources belonged, the patent laws acted as a curse. In the global scenario the indigenous states which have rich biological resources are in developing stage are unable to use their traditional knowledge in a commercial scale. The exponential increase in commercialization of biological resources has increased the 'Biopiracy' throughout the world. Biopiracy is defined as a process, in which living resources or traditional knowledge and practices are patented, thus applying intellectual property restrictions to their use. The present study deals with the analysis of the patent laws as a boon or curse against Biopiracy.

KEYWORDS: Patent Laws, Biopiracy, Boon, Curse, Traditional Knowledge.

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#### INTRODUCTION

The earth has a very vast and diverse reservoir of natural resources. The development of international boundaries has divided earth into different geographical locations. These international boundaries have created a number of countries or nations. Some countries have very rich biological diversity while others have less<sup>1</sup>. The advancement in the field of science and technology has made some countries progressed enormously. This advancement has been in the field of agriculture, pharmaceutical, biotechnology and medical industries. The developed countries have various global companies that have a global market. Their progress has induced them to utilize the biological resources for producing various products. These products are commercially marketed throughout the world. In order to develop new products these companies have used the traditional knowledge and the biological resources of other geographical locations or countries. This misappropriation on biological resources and traditional knowledge is known as 'biopiracy'<sup>2</sup>.

Biopiracy infringes the rights of indigenous communities of its biological resources and its traditional knowledge. These rights of indigenous communities are overtaken by the monopoly rights of those who have exploited the indigenous knowledge and biological resources. The practice of biopiracy has developed inequality among the nations of the world. The biopiracy by developed nations is touching the height of theft of biological resources and traditional knowledge. The use of patent laws along with biopiracy has raised the question in front of the international communities to formulate new legislations against such act.

#### THE ORIGIN OF BIOPIRACY

The term biopiracy was apparently for the first time used by a nongovernmental worker of Canada. This was because he encountered some illegal exploitation during the course of his work at the international rural advancement foundation<sup>3</sup>. The concept of biopiracy persuaded frustration with the appropriation and monopolization of long held medicinal and agricultural knowledge about nature as well as the plants, animals and their components<sup>4</sup>. The mismanagement occurs when companies take traditional knowledge from indigenous communities, keeping them in the dark. This is basically theft of knowledge that has been carried out for generations. In the year 1993, Crosby described that bioprospecting has been carried out since the colonial period, when exploration was done mainly to exploit the indigenous people and their knowledge<sup>5</sup>. Thus biopiracy is an evolution of this exploitation. South, in the year 2007 described that not the colonial powers but the corporations exploited the indigenous people and their knowledge<sup>6</sup>. Further it was deducted that biopiracy arose due to the increase in inequality resulting from modern technological and institutional structures. Goyes and South, in the year 2016 stated that this can be evidenced in Colombia where, these

structures, courts, trade agreements and patents tend to favors the interest of powerful corporations and western institutions over indigenous and local people<sup>7</sup>. In Colombia, this resulted in prohibiting the farmers from collecting and planting seeds from their own lands. Thus, Goyes and south expanded the concept of biopiracy by describing it as the process of grabbing the land of indigenous people by technically legal method.

Various Scholars have defined biopiracy in different manners. Some define biopiracy is to agree on the element of exploitation through the lack of compensation and recognition. Others like Reid define biopiracy as the method of taking indigenous peoples knowledge without compensation<sup>8</sup>. Shiva, in the year 2001 defined biopiracy as the process of using the intellectual property systems to legitimize the whole ownership and control of biological resources and their products<sup>9</sup>.

The initiation of the patent laws began in the 14<sup>th</sup> century in Venice, where patents and the intellectual property were the modes of regarding innovation and knowledge<sup>10</sup>. The Intellectual property rights were exclusively linked with the field of industrial inventions, arts and literature. At that time it was not possible to foresee the development that has taken place in the field of biotechnology, because the activities involved in those inventions were subjected to casual relationship. However, according to the classical view the patent laws do not recognize the living materials. But in the last century there have been significant developments in the field of agriculture and biology that has demanded for an intellectual property right system with respect to the agriculture and biological inventions.

The first patent in life forms was issued in Finland in 1843 and in the United States in 1873 a patent was granted for isolated yeast<sup>11</sup>. The United States plant patent act that was passed in 1930, provided protection to both asexually propagated and sexually propagated varieties of plant varieties<sup>12</sup>. In the decade of 1970's various events took place that incorporated intellectual property rights with the agricultural and biological inventions. However, before this neither of the patent laws of US nor of Europe had any provisions in relation to patenting of living organisms. In 1975, a French company failed on technicality to patent a dwarf egg laying chicken hen produced by a breeding process that exploited a sex linked recessive dwarfism gene<sup>13</sup>. In the Diamond v. Chakra arty case the US Supreme Court granted patent for a genetically engineered bacterium that has the property of breaking down oil<sup>14</sup>. The court granted the patent taking into consideration that the microorganism was not a product of nature but was an invention. This grant of patent increased the number of patent applications for biological material. The decade of 1991-2000 witnessed the record number of patent in Europe of 1.3million<sup>15</sup>.

On the basis of legal grounds biopiracy is questionable but in absence of legal provisions it cannot be regarded as a crime. This does not mean that one is free to commit biopiracy. For centuries the fundamental norm of common heritage is very useful in the management of natural resource<sup>16</sup>. The natural places of the globe which includes the places like Antarctica, space, the oceans and mountain peaks have been regarded as genetic resources relevant to food and agriculture by Food and Agriculture organization (FAO)<sup>17</sup>. Food and Agriculture Organization universally accepted the principle that nobody can claim over the natural resources of the earth, as it acts as a disadvantage to the indigenous communities and its traditional knowledge. Biopiracy of these natural resources strengthen the developed nations and weakens the developing or underdeveloped nations. The process of Intellectual property is best suited to the industrialized societies which have an advanced research and development facility. The developing and under developed nations are behind due to the lack of research and development. This leads them to the lack of ability to innovate and invent. For this purpose the intellectual property rights may act as a defense for them. The developed nations have been using the legal instruments in their favour and pose their monopoly in the world. In this way the global standard for patenting the biological resources is inequitable. Biopiracy not only hinders the traditional knowledge and heritage of developing and under developed nations but also pose a potential threat to the economic and biological interest of these nations. Biopiracy also intrudes to the sovereignty of a nation by securing patents of generic resources that have been derived from the native species and the knowledge possessed by the indigenous people of that nation. This indicates the violation of the concept of common heritage of mankind, along with the violation of the states sovereign rights to its own natural resources<sup>18</sup>.

It should be taken into consideration that intellectual property regimes are essential for technological and economical growth. The western nations exploit the indigenous knowledge through a globalized biased patent system<sup>19</sup>. Actually the global patent system has been established by the western developed nations, which recognize only some forms of proof of knowledge<sup>20</sup>. The law courts do not take into consideration the history of traditional knowledge, as a result of this the western nations seeks profit from the indigenous knowledge and utilize this biased legal system. The globalised legal patent system enables the biopiracy by western nations that results in patented profitable products<sup>21</sup>. The power of these western nations also enables them to defend biopiracy.

# THE LINK BETWEEN BIOLOGICAL RESOURCES AND TRADITIONAL KNOWLEDGE

In developing and under developed nations the biological resources and the traditional knowledge related to them are fundamental to indigenous community. These biological resources act

as a reasonable alternative mode of health care and nutrition which also provide employment and income generation to these nations. For example, 90% of global rice is produced by the South East Asia which is a significant staple crop for majority of Asian families that provide 80% of the daily intake calories along with significant levels of employment and income<sup>22</sup>. The scientific communities utilize the traditional knowledge of different medicinal plants and their healing properties to develop new drugs. The traditional medicines contribute exceptionally to the global market. However the biological resources and the traditional knowledge contribute to the cultural expression and the assertions of local authorities<sup>23</sup>.

#### THE FADING OF TRADITIONAL KNOWLEDGE:

The present patent system has faded the traditional knowledge in the globe. The scenario in the field of biotechnology raises a question on the present patent system. From the technological point of view the process of patenting involves three criteria: novelty, inventive and industrial applicability<sup>24</sup>. The EPC (European Patent Convention) does not define 'invention' but Article 52 section 2 lists several categories which are not patentable 'as such'<sup>25</sup>. On the grounds of the principle of novelty and inventiveness, the patents based on the traditional knowledge are disqualified as they are subjected to a mere discovery rather than invention. The global companies that apply for patents from natural resources just discover them from the traditional knowledge obtained from the indigenous societies that is prevalent in these areas for decades.

Commercialization of natural resources has created an adverse effect on the native people. The global companies for their profit have replaced the old practices of farming and introduced use of chemical fertilizers for increased productivity. The heavy use of chemical has degraded the fertility of soil. The repeated use of the chemical fertilizers has even turned some fields to barren land. Thus the traditional knowledge is vital for the indigenous societies; with the fading of this knowledge these societies have paid a heavy price.

In India TKDL (Traditional knowledge digital library) has been set up to preserve the traditional knowledge. The TKDL has been set by a joint collaboration of CSIR (Ministry of Science and Technology) and (AYUSH) (Ministry of Health and family welfare)<sup>26</sup>. The TKDL authority incorporates experts from various fields like traditional medicine, patent and information technology (IT). The TKDL authorities are documenting the traditional knowledge available throughout the India and converting it into a digital format, which is called as a digital library. This digital library can be presented before the patent evaluators at the international level to defend the patents granted for subject matter that has been isolated from the Indian traditional knowledge. The TKDL database consists of about 2.90 lakh medicinal formulations.

#### **BIOPIRACY-THEFT OF ECONOMIC DEVELOPMENT:**

Biopiracy can also be termed as both thefts of natural resources along with the theft of economic development<sup>27</sup>. For instance the global companies promise to give jobs and working opportunities to the indigenous people in return for granting access to their biological resources and traditional knowledge. But the companies betray them, they steal the traditional knowledge of the indigenous people and develop their own product and the indigenous people remain unaware of the product being produced and developed from their traditional knowledge. In other words they do not provide any information related to the traditional knowledge to the indigenous communities. The reason behind is that they do not want to share profit with these indigenous communities. In this way, biopiracy lead to theft of economic resources and thereby economic development.

#### **CULTURAL AND ETHICAL RESPONSIBILITIES:**

It has been observed that the indigenous people often do not share the traditional knowledge of their biological resources. There cultural ethics encourages them to preserve their traditional knowledge for the welfare of their people. However, in the modern world the greedy companies for profit steal the traditional knowledge from the indigenous people in the name of welfare of the people. Once they obtain the useful information of the biological resources, they produce their desired products and acquire huge profits. As a result of this the poor indigenous communities remain poor and the rich exploiters accumulating more and more wealth.

The native communities or tribes are generally not acknowledged for their knowledge in a manner that they should ethically have been<sup>28</sup>. In the interest of the developing world these communities should also be given equal importance for their traditional knowledge and biological resources. It is the ethical and cultural responsibility of the developed nations to recognize the importance of these communities of the developing and underdeveloped nations. It is very unfortunate that people have failed to be responsible and good human being in the quest to become a richer or a more powerful individual<sup>29</sup>.

#### **IMPORTANT BIOPIRACY CASES**

#### The Neem Case

The neem tree (*Azadirachta indica*), which translates as the 'free tree', is a member of the mahogany family. It is indigenous to the Indian subcontinent, where it has been used in agriculture, medicine and cosmetics for centuries. The patent for *Azadirachta indica* (Neem) was granted in the year 1994, to the US based company WR Grace, for a fungicide made from neem oil<sup>30</sup>. The patent was opposed by many of the NGOs and environmental organizations stating that it was a biopiracy.

As a result of this, the European patent office withdrew this patent in May, 2000 concluding that nothing has been invented and that the traditional knowledge and use of neem have been common in India for many decades.

#### The Basmati Rice Case

An American company Rice Tech Inc. was granted patent for using the term Basmati for all the aromatic rice grown outside India. Most of the Asian countries as the grant of this patent were affected by this patent for trade. Since Basmati rice is traditionally grown in India and neighboring countries, it was stated that granting patent to Rice Tec Inc. violated the Geographical Indications Act under the TRIPS agreement<sup>31</sup>. This resulted in diplomatic war between US and India. India took the matter to the WTO (World Trade Organization) indicating the patent was granted setting aside the provisions of TRIPS. Later on it was decided to reject the patent for this.

#### The Sacha Inchi Case

*Plukenetia volubilis* Linneo (also known as Sacha inchi), traditionally has been cultivated by the people of the Amazon for over 3000 years which is highly concentrated in fatty acids. Various companies in the cosmetic and food markets have been in queue to pursue patents for the compounds derived from this plant. The Peruvian national anti biopiracy commission fought for the illegitimate patents brought for this plant. The outcome was the cancellation of the patent granted to green tech company from France<sup>32</sup>.

#### The Maca Case

The plant Maca (*Lepidium meyenii*) acts as a tonic, helps in consolidating fractures, rebalances the menstrual cycle and is especially renowned as an aphrodisiac for both men and women. In modern times the Aphrodisiac market is highly lucrative; it has attracted many western health food companies. This resulted in patent application for Maca by various multinational companies. The European patent office on the basis of the Peruvian national anti biopiracy commission rejected several patents on Maca<sup>33</sup>.

#### The Novartis V. Union of India Case

The supreme of India in its landmark judgment in the case of Novartis AG Vs Union of India rejected to grant patent to the Swiss drug pharma company, Novartis for its anti cancer drug Gleevec. The Court stated that It was clear from the Zimmerman patent that imatinib mesylate itself was not new and did not qualify the test of *invention* as laid down in section 2(1)(j) and section 2(1)(ja) of the Patents Act,  $1970^{34}$ .

#### The Turmeric Case

Turmeric (*Curcuma longa*) is well known tropical herb grown in east India. Turmeric powder has been widely used in India as a medicine, a food ingredient and a dye for decades. In 1995, United States awarded patent on turmeric to University of Mississippi medical center for wound healing property. It was granted full rights to sell it at the global market. However, after two years CSIR (Council of Scientific and Industrial Research) challenged the patent being granted questioning the novelty of the discovery. As a result the United States Patent and Trademark Office cancelled the patent being granted, due to lack of novelty<sup>35</sup>.

#### The Ashwagandha Case

An American Japanese firms applied for the patents regarding formulations or extracts of Ashwagandha (*Withania somnifera*). The patent application was applied for curing arthritis by using the extracts of Ashwagandha . Natreon Inc. and America based multinational company filed a patent application in European patent office on Ashwagandha describing its long use in treatment of anxiety, induced stress, depression, insomnia, gastric ulcers and convulsions. However, out of the several patents granted in favour of Ashwagandha, India was successful in revolving only one. In order to support the rejection of the patent, the Indian authorities submitting evidences from Traditional knowledge Digital Library (TKDL). The conclusion was that EPO decided to reject the American firms claims over the Indian Ginseng<sup>36</sup>.

#### The Mint and Andrographis Case

The M/S Livzon pharmaceutical group Inc. Guangdong; a Chinese pharmaceutical company filed a patent at EPO stating the novelty of Pudina (mint) and Kalamegha (andrographis) for the therapy of H5N1 avian influenza. In a joint venture of India's CSIR and TKDL, unveiled the age long use of pudina and kalamegha in India since ages for influenza and epidemic fevers. India's TKDL sent a letter to the EPO explaining the evaluators of patenting, regarding the traditional medicinal properties of pudina and kalamegha in India. After obtaining elaborated proofs form CSIR the EPO called off the decision to grant patent to Livzon. Thus Indian attempt to restrict the biopiracy to patent the use of medicinal plants, pudina and Kalamegha by Chinese company was successful<sup>37</sup>.

#### The Aloe Vera Case

A large number of countries worldwide applied for the patent of Aloe Vera (*Aloe barbadensis*). The use of Aloe Vera in India are very old. The ancient medicine system of Ayurveda

and Siddha books already exhibits various medicinal properties of aloe Vera. This was expressed by India at the international level to the patenting authorities and various patent applications were withdrawn<sup>38</sup>.

#### The Momordica Charantia, Solanumm Elongena and Syzygium Cumini Case

The traditional medicinal use of Syzygium *cumini*, popularly known as jamun: *Momordica charantia* popularly known as bittergourd or karela and *Solanumm elongena* popularly known as brinjal or eggplant has been clearly indicated in the ancient treatment therapies of India. The ancient Indian medical treatment therapies were based on rich herbal formulations obtained from different herbal plants and trees. Various pharmaceutical companies from different nations have been trying to patent these herbs. But India has successfully defended against the biopiracy of these herbs, since its traditional knowledge belongs to India<sup>39</sup>.

#### The Kava, Ayahuasca, Quinoa, Hoodia Cactus Case

In the pacific region a cash crop known as 'Kava' is grown. Likely Quinoa, a staple food crop is grown in the andes. Hoodia cactus is that of South Africa. In amazon basin a ceremonial drink called as Ayahuasca is commonly consumed. All these have been tried to be patented by various developed nations. However some of them have been protected against biopiracy while others have been patented<sup>40</sup>.

#### THE PATENT LAWS AGAINST BIOPIRACY

Biopiracy is found in three forms<sup>41</sup>

#### **Bio-prospecting-**

The first type of biopiracy is called as bio-prospecting. Bio-prospecting is the process by which someone discovers an unknown plant or organism. After the discovery of this plant or organisms, these plants or organisms are further taken for discovery of some unknown properties that can be applied for patent. However most of these discoveries include the traditional knowledge of the indigenous people that is known to the indigenous communities for decades.

#### Discovery of Unknown Properties in Known Plants and Organisms

The second type of biopiracy deals with the discovery of the plants and organisms that is slightly different from the regular species, which are subject able to patent. For example, the patent for Enola bean. In the year 1999, the United States Patent Office ("USPO") granted a patent to Larry Proctor, for the claim of developing a new field soybean variety. Proctor achieved this "invention" by simply purchasing some beans from the market in Mexico and planting them in Colorado. He subjected these beans for self-pollination and further harvested them for three times, the resulting Enola bean remains yellow in color in spite of season change. For this invention the USPO granted the patent but it was challenged by the International Center for Tropical Agriculture ("ICTA"). Initially the USPO upheld the patent concluding that color was enough to meet the novelty but later it rejected the novelty of Enola bean.

#### Exploitation of Traditional Knowledge-

The third type of biopiracy is the exploitation of traditional knowledge. For example the case of pozol patent, this resembles the instance of exploitation of traditional knowledge. The Mayan people for centuries have been drinking a fermented Mexican drink called as pozol. This drink is health-promoting and bears antibacterial properties. Exploiting these properties of pozol, a Dutch corporation and the University of Minnesota isolated *Bacillus subtilis* from pozol and used it as a natural inhibitor of unwanted flora in foods and feeds. A patent was granted for this which was just exploiting the traditional knowledge of the Mayan community. Consequently, there was a big argument for this grant of patent. The Mexican government then took various initiatives against this patent so as to withdraw it.

Thus biopiracy can be marked as a complicated matter that requires various laws to be handled. Biopiracy links to the laws that of intellectual property rights, environment, biodiversity, international, national, treaties and agreements. In addition to these various amendments to these laws are also required to be formulated. Some of the international and national laws against biopiracy are described as under

#### THE INTERNATIONAL PATENT LAWS AGAINST BIOPIRACY:

#### The Trips Agreement 42

The world trade organization, in the year 1995 for providing protection to the intellectual property rights introduced the Trade related aspects of intellectual property rights or TRIPS. The main objective of TRIPS is to enhance the ideas by providing protection to its intellectual property rights of its owners and further rewarding their innovativeness and ingenuity. The TRIPS agreement has been recognized as an "impressive" document for its "comprehensive scope and coverage," that makes it one of the "most important multilateral instruments in this field. As a part of the WTO, the TRIPS agreement has been formulated according to the needs of industrialized nations which on the other hand put pressure on developing nations. The Article 27 of the TRIPS agreement deals with the requirements for patentability. Article 27 section 1 states that "patents shall be available for any

inventions, when products or processes involve an inventive step and are capable of industrial application. Article 27 clearly states that member states may interpret "inventive step" and "capable of industrial application" so that the patent is "non-obvious" and "useful. These broad standards of TRIPS develop "a general principle of eligibility" for patents.

#### The Doctrine of Sui Generis 43

The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore discussed an element that might be a part of distinct *sui generis* legal system which specifically protects traditional knowledge ("TK"). On the second session of the Committee, that was held in Geneva from 10th to 14<sup>th</sup> of December 2001, a number of delegations from different regions laid down the relevance of examining possible modalities of intellectual property ("IP") *sui generis* systems for the protection of traditional knowledge. The Latin word *sui generis* generally means generated by one self which also means, 'of its own kind' or 'unique'. The effectiveness of *sui generis* system of plant variety protection has become rigorous because of the absence of its definition in Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. However, India has legislated the *sui generis* law, the Protection of Plant Variety and Farmers' Rights in 2001 and notified its rule in 2003. The Article 27 section 3 (b) of the TRIPs agreement states that the member state protect plant varieties either by patent or under a sui generis system, or both. It however does not indicate the nature of the sui generis system. Consequently, this results in a controversy between the developed and developing countries.

#### The Doctrine of Common Heritage of Mankind <sup>44</sup>

According to the international Food and Agriculture Organization, the plant genetic resources are a common heritage of mankind; therefore it should be made available without restriction. This is because nobody can claim sovereignty over these resources. Many countries of the Food and Agriculture Organization (FAO) of the United Nations passed a Resolution 8/83 with the object of international undertaking on plant genetic resources (1983). This undertaking provides free access to all germplasm, like developing elite varieties and breeding materials. However, developed countries opposed this resolution, by arguing that this does not honor the proprietary nature of breeding materials and finished varieties. As a result of this compliance the resolution 8/83 was not binding. In other words, most of the developed countries depicted that they would be unable to support the undertaking unless significant free access was included. Several developing countries favored to choose not to adhere to the undertaking, especially China, Brazil and many South-East Asian countries. Fundamentally the concept of farmers' rights is different from the existing plant breeders'

rights system. The breeders can obtain intellectual property protection supported by the law, to obtain compensation for improving plant varieties. The Plant breeders' rights provide new variety developers to monopoly rents for a limited period of time. These rents act as economic incentives for new varietal development. Thus, the farmers' rights system regulates a non-compulsory moral obligation to developing countries for past contributions to crop genetic improvements and the plant breeders' rights regulates the creating incentives for future innovation. The Convention on Biological Diversity (CBD) indicates two controversies that surround plant genetic resources (PGRs). One controversy is over property rights governing PGRs and the distribution of benefits from their use. The second controversy is over the adequacy of measures to maintain crop genetic diversity. The Convention on Biological Diversity exhibits wider international acceptance of stricter property rights over PGRs and the need for multilateral assistance for PGR conservation.

#### The Convention on Biological Diversity<sup>45</sup>

In the year 1992, an international agreement was adopted at the Earth summit in Rio de Janeiro. This international agreement was called as Convention on Biological Diversity (CBD). It has three main objectives; to conserve biological diversity, to use its components in a sustainable way, to share fairly and equitably the benefits arising from the use of genetic resources. This agreement was negotiated under the guidance of the United Nations. More than 150 leaders from different nations signed this agreement, under the official program of United Nations Conference on Environment and Development. At present, the convention is one of the most widely accepted international treaties on environmental issues. About 194 member countries are a part of this international treaty. The convention on biological diversity takes a flexible approach to implementation. The convention deals with identification of general goals and policies, and the countries associated with it are free to determine how they want to implement them. The convention on biological diversity not only recognizes the dependency of indigenous people on biodiversity but also their unique role in conserving life in earth. It not only recognizes the states sovereignty over its own resources, but also prohibits the exploitation of these resources without the prior permission of such state.

#### The Nagoya Protocol<sup>46</sup>

The Nagoya Protocol deals with the genetic resources that are covered by the Convention on Biological Diversity (CBD), and to the benefits arising from the utilization of these genetic resources. The Nagoya Protocol also includes traditional knowledge (TK) associated with genetic resources and the benefits arising from its utilization. The Nagoya Protocol is a supplementary agreement to the Convention on Biological Diversity. It provides a transparent legal framework for the effective implementation of one of the three objectives of the CBD i.e. the fair and equitable sharing of benefits arising out of the utilization of genetic resources. The Nagoya Protocol was adopted on 29 October 2010 in Nagoya, Japan and came into force on 12 October 2014, 90 days after the deposit of the fiftieth instrument of ratification. Its main objective is the fair and equitable sharing of benefits arising from the utilization of genetic resources, and thereby contributing to the conservation and sustainable use of biodiversity. The Nagoya protocol specifies how the CBD can be applied. The protocol is associated with Access and Benefit sharing (ABS). Its aim is better regulations of access to genetic resources and encourages states to set up an agency to which firms and researchers must request for operating licenses. It also suggests that the states should also ensure the setting up and running of an equitable mechanism of sharing any benefits arising from the use of resources.

#### THE NATIONAL PATENT LAWS AGAINST BOIPIRACY:

#### *The Patent Act, 1970*<sup>47</sup>

The Indian Patent act was enacted in 1970. The patent act, 1970 was amended several times till 2005 according to the TRIPS agreement. The main features of the act include: product patent, compulsory licensing, exclusive marketing rights, and extending patent term to 20 years. To protect the knowledge, innovations and practices associated with the biological resources that are often being used under traditional knowledge, it was suggested to adopt the sui generis system that is different from the present IPR system.

#### The Protection of Plant Varieties and Farmers Right Act, 2001<sup>48</sup>

The Indian Patent Act, 1970 excluded agriculture and horticultural methods of production from patentability. For this purpose, the sui generis system for protection of plant varieties was created that includes the rights of breeders, farmers and village communities, and also takes care for equitable sharing of benefits. The objectives of the Act are as follows:

- (i) To develop effective system for protection of plant varieties.
- (ii) To protect the rights of farmers and plant breeders.
- (iii) To encourage the investment for research and development and to contribute growth of the seed industry.
- (iv) To provide high quality seeds and planting materials to farmers.

The act appreciates the role of farmers and the contribution of traditional, rural and tribal communities to the country. This act protects the rights of farmers by benefit sharing. The act also suggests the establishment of a National Gene Fund to promote the conservation and sustainable use of genetic resources to protect plant varieties.

#### The Biological Diversity Act, 200249

The Biological Diversity Act, 2002 deals with the preservation of biological diversity in India, and provides mechanism for equitable sharing of benefits arising out of the use of traditional biological resources and knowledge. The Act was created to meet the obligations under Convention on Biological Diversity (CBD), to which India is a party. The section 2(b) of this act defines the term biodiversity. According to the definition biodiversity is "the variability among living organisms from all sources and the ecological complexes of which they are part, and includes diversity within species or between species and of eco-systems". This act defines biological resources as, "plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material. Some of the main provisions of this act are as follows:

- 1. To prohibit the transfer of Indian genetic material without the permission from the government of India.
- 2. To prohibit the claiming of anyone on intellectual property right, over biodiversity or its traditional knowledge without the permission of the government of India.
- 3. To restrict the collection and use of native flora and fauna by Indian nationals while exempting the local communities.
- 4. To encourage the sharing of benefits arising from the use of biodiversity.

#### The Traditional Knowledge Digital Library (TKDL)<sup>50</sup>

In 2001, a digital library on traditional knowledge of India was established with the joint collaboration of CSIR (council of scientific and industrial research) and Ministry of AYUSH. The main objective of this library is to protect the ancient and traditional knowledge of India from exploitation through biopiracy and unethical patents, by documenting it electronically and classifying it as per international patent classification systems. TKDL Library contains around data of 80,000 formulations in Ayurveda, 1,000,000 formulations of Unani and 12,000 formulations of Siddha. In addition to this it has also signed agreements with leading international patent office's such as European Patent Office (EPO), United Kingdom Trademark & Patent Office (UKPTO) and the United States Patent and Trademark Office to protect traditional knowledge from biopiracy.

According to the CSIR the success has been achieved in 219 cases where the patent applications have either been withdrawn/cancelled/declared dead/terminated on the basis of TKDL submissions.

#### Geographical Indications of Goods (Registrations and Protection) Act, 2003<sup>51</sup>

With an aim to protect the geographical indications of the country, Geographical Indication of Goods Act (2003) which is a sui generis legislation was enacted by union government of India. Under this act a product is defined by a geographical area where, it is traditionally found. A geographical indication (GI) is a name or sign that is used for certain products which corresponds to a specific geographical location or origin (e.g. a town, region, or country). The use of a GI ensures that the product possesses certain qualities, that it is made according to traditional methods, or enjoys a certain reputation, due to its geographical origin. In 2004-05, Darjeeling tea became the first GI tagged product in India. Since then till September 2010, 184 products had been added to the list.

#### CONCLUSION

The legal tools developed by the developed nations have exploited the underdeveloped and developing nations. With the help of legal tools the developing and underdeveloped nations have been exploited by biopiracy. The commercialization of the traditional knowledge of indigenous people has exerted biopiracy to a very alarming level. The recent cases of biopiracy depict the need to develop better regulations through various effective laws. The disclosure norms related to an invention should be such that steps of invention are clear and distinctive. This will definitely hold the patent war between the nations. The indigenous people do also have the rights over their traditional knowledge of the indigenous people, and should stop exploiting the use of patent laws for their economic development. Both justice and morality exhibit that the developed nations should treat indigenous people of developing and underdeveloped nations with respect. Thus, in the present scenario the patent laws have acted both as a curse and a boon against biopiracy.

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