“How can Thailand legally deal with the problem of bio-prospecting?”

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Abstract

Bio-prospecting has become a controversial issue under IPRs scheme when TRIPs allow monopoly rights of the product or process derived of biological resources without recognizing the ownership of the biological resources. TRIPs has written to protect the intellectual property rights around the world by bringing contracting parties under common international rules with an effective enforcement mechanism. As a consequence, many nations especially developing nations who have abundant biological resources consider that they could not be of great benefit from being an owner of these resources under the TRIPs' IPRs scheme as long as the TRIPs agreement still doesn't recognize the sovereignty of state over biological resources. One of the solutions for the bio-prospecting problem is to make change of a patent law by adding the requirement which recognizes the sovereignty of state over biological resources. However, this thesis has explained later that adding extra criteria of patentability by amending the patent law under the TRIPs is politically difficult. Therefore, this thesis sees the solution to the problem is to find out how the country can control the access and use of biological resources in a fair and equitable matter before it applies for patent protection. This thesis has chosen Thailand as a reference because Thailand still does not have comprehensive condition and tool that can deal with the bio-prospecting problem.

This thesis has proposed a solution to the bio-prospecting problem by placing conditions and tools in the legislation or so called "Biodiversity Legislation". The thesis views that the legislation equipped with the conditions and tools will be the best way to escape the rigidity of the TRIPs agreement and political deadlocks and additionally can focus on any biodiversity issues in the future. It should be noted that the conditions and tools to be equipped in the legislation are Prior Informed Consent, the Benefit Sharing Scheme and Social Impact Assessment. These conditions and tools are a reflection of the recognition of sovereignty of state over biological resources. This thesis has concluded that a new "Biodiversity Legislation" equipped with conditions and tools will help Thailand to deal with the problem of bio-prospecting effectively and efficiency under the international rule and keep up Thailand competitiveness and benefit from bio-prospecting activities and technological development in the capitalistic world.

DEDICATION

To my Mother and Father,
who never had the chance to see
the successful accomplishment of their son.

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Many thanks to Ms. Ilona Cheyne, my supervisor, whose opinion and recommendations enabled me to complete the necessary research, and to draw conclusions concerning the workings of a city in a country foreign to me.

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A great part of my success must be attributed to my sister, Tiparat Phimolsathien, whose special encouragement sustained me through my difficult time throughout my study.

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Chapter 1: Introduction

This thesis was written to find out *"how can Thailand legally deal with the problem of bio-prospecting?"*

1.1: Purpose of the Study

Bio-prospecting[1] has become a controversial issue under the intellectual property protection scheme when Patent law and Plant Variety Protection laws allow the creation of monopoly rights over products or processes derived from biological resources without recognizing the original ownership of the biological resources or, in the other words, without recognizing the sovereignty of States over the biological resources contained within their territory. Those monopoly rights include making, using, offering for sale, selling, or importing the product, right to assign, transfer by succession, and to conclude licensing contracts[2]. The term of protection is available before the expiration of a period of twenty years counted from the filing date[3]. The question is whether countries those own biological resources should let others have rights over products and processes derived from their biological resources and if so, under what conditions. This question is sharpened by the existence of the principle of international law that recognizes States as having sovereignty to control and permit the use of natural resources whereas, in contrast, patent law ignores the sovereignty of the State over biological resources. Some academic writers have also argued that the right of self-determination has relevance to the rights of owners of traditional medicine when it comes to exploitation, in particular the commercial exploitation[4].

The concern about the problem of bio-prospecting was exacerbated when the the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs)

1 The word "bio-prospecting" was introduced when scientists went out in the field to search for the benefits of biological resources for the production of the product and process. Bio-prospecting is not new. People around the world have been bio-prospecting for centuries for the product and process such as learning that delicious plant roots had higher sugar content and can be used for the production of sugar or discovering that a particular plant can be used for medicine, for example, aspirin.

2 Agreement on Trade Related Aspects of Intellectual Property Rights/ art 28/ (http://doconline.wto.org)

3 Agreement on Trade Related Aspects of Intellectual Property Rights/ art 33/ (http://doconline.wto.org)

4 Christopher Health and Sabine Weidlich, "Intellectual Property: Suitable for Protecting Traditional Medicines" Intellectual Property Quarterly 2003, p.235

came into force[5]. TRIPs was written to narrow the differences between the protection of intellectual property rights around the world, and by bringing them under common international rules with an effective enforcement mechanism[6]. For example, the TRIPs agreement requires WTO Members to establish minimum levels of intellectual property protection by introducing or amending patent law to conform to TRIPs. The linkage between the problem of bio-prospecting and TRIPs arose because Members of the WTO are required by TRIPs to allow biological resources to be subject to patent protection as a product or process[7]. As a consequence, anybody can take valuable biological resources, even without the consent of the State that owns them, and develop them as a product or process that qualifies for patentability thereby obtaining monopoly rights over the product or process without being constrained by the principle of the sovereignty of States over the biological resources. As a result, many nations, especially developing nations, consider that they are not deriving great benefit from being the owner of these resources if TRIPs agreement still does not recognize the sovereignty of States over biological resources. This is an important problem because an estimated 90 percent of all genetic resources are located in the tropical and subtropical regions of Africa, Asia and South America[8].

One of the solutions for the problem of bio-prospecting would be to change patent law by adding a requirement that the sovereignty of States over biological resources be acknowledged by making State consent a criterion of patentability. However, as will be explained in more details in chapter 4, adding extra criteria of patentability by amending the patent law under the TRIPs agreement is a difficult option because of the political deadlock at the international level. Briefly, developed countries like the US, EU, Japan those have lead in technological development but

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5 Preamble of the Agreement on Trade Related Aspects of Intellectual Property Rights

6 TRIPs agreement/ Art41.1 states that Members shall ensure that enforcement procedures as specified in this Part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.

7 TRIPs agreement/ Art 27.1 stated that Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

8 Martin A. Girsberger;, "*The Protection of Traditional Plant Genetic Resources for Food and Agriculture and the Related Know-How by Intellectual Property Rights in International Law-The Current Legal Environment*"; The Journal of World Intellectual Property Vol. 1 No. 6 (November 1998) p. 1017

lack highly varied biological resources may be opposed to adding extra criteria of patentability, whereas developing countries who own valuable biological resources but lack technological expertise would strongly like to see a compulsory requirement which recognizes their State sovereignty. Therefore developing countries have to find an alternative means of protecting their biological resources, by finding a way to control the access and use of biological resources in a fair and equitable matter before any application for patent protection.

This thesis will address how the problem of bio-prospecting could be answered by balancing the rights of the innovator and the sovereign right of States over biological resources. It will focus particularly on Thailand as an example of a developing country that is a Member of the WTO and therefore TRIPs and possesses many valuable biological resources, and how it can deal with the problem of bio-prospecting before an application for patent protection for products or processes is made. In other words, the purpose of this thesis is to explore problem of bio-prospecting in order to protect the value of developing countries' biodiversity through unregulated bio-prospecting, using the specific example of Thailand. This thesis will propose conditions and a tool to control the use of biological resources through exercise sovereign rights of the State which will solve the problem of bio-prospecting. Those conditions and a tool are Prior Informed Consent, Benefit Sharing, and Social Impact Assessment respectively. The relevance, applicability and benefits of these conditions and tool will be examined and an analysis made of how the conditions and tool could be introduced effectively without contravening with the TRIPs agreement. Thailand will be used as an example of how could the conditions and tool could be put into practice.

1.2. Background of the Study

Bio-prospecting has been defined in numerous ways such as "the search for commercially valuable bio-chemicals and genetic resources in plants, animals and micro-organisms"[9], "the search for genes and chemicals in biological resources to

9 The national history Museum, "SYS-RESOURCE: Bio-prospecting Policy" , http://www.nhm.ac.uk/science/rco/sysresource/bioprospecting.html (21 August 2008)

produce commercial products such as pathogen-resistant crops and medicines"[10], "the exploration of biodiversity for commercially valuable genetic and biochemical resources"[11], "the research, collection and utilization of biological and genetic resources, for purposes of applying the knowledge derived therefore for scientific and/or commercial purposes"[12], or "the systematic search for genes, natural products, designs and whole organisms in wildlife which have the potential for product development, without disruption to nature and is therefore a means of promoting conservation and sustainable use of biodiversity"[13]. According to the above definitions, it seems to be that the main objective of "bio-prospecting" is the commercial exploitation of natural resources in particular biological resources for the exploitation of products and processes.

In the 21st century, the importance of bio-prospecting has been widely seen from the advent of biotechnology[14] and genetic engineering[15] which resulted in an increase of the value of biological resources, especially in developed countries possessing advanced technology. This can be seen in the importance of economic

10 Department for International Development, "Bioprospecting project", http://www.odi.org.uk/tropics/projects/3308.htm (25 September 2005)

11 Katy Moran , "Bio-prospecting: lessons from benefit-sharing experiences", http://www.ksg.harvard.edu/cid/cidbiotech/IJBT/ijbt2_moran.htm" (26 October 2005)

12 Lewis & Clark College, "University of Oregon, International Environmental Law Project", http://www.lclark.edu/org/ielp/philippinereg.html (5 November 2005)

13 National Park Service, "what is Bio-prospecting", "http://www.nature.nps.gov/benefitssharing/whatis.htm" (6 November 2005)

14 The importance of the biotechnology in terms of production can be seen that Globally, the four main GM crops being grown commercially are soybean (36.5 million hectares, or more than 62 per cent of the global soybean area), maize (19 per cent), cotton (13 per cent) and oilseed rape (5 per cent). In 2002, GM crops grown worldwide covered twice the land area of Britain (58.7 million hectares), a 12 per cent increase on 2001 and this figure is growing rapidly. By land area, the vast majority (99 per cent) of GM crops are grown in four countries: the US, Argentina, Canada and China, with the US accounting for around two-thirds of the world total. GM crops are also commercially grown in Australia, Bulgaria, Colombia, Germany, Honduras, India, Indonesia, Mexico, Romania, South Africa, Spain and Uruguay. Globally, approximately 6 million farmers in these 16 countries (7 developed; 9 developing) grow GM crops, with 75 per cent of these farmers coming from the developing world. It shall be understood that the product/ process derived from biotechnology may not necessarily be in the form of canned food, cheese, or any finished product but it can be a raw material (fresh products) including any plant varieties such as a frost –resistant tomato plant, disease-resistant asparagus, higher yielding strawberry, herbicide-tolerant tobacco, nutritious varieties of corn, cholesterol-free meat which result of the manipulation of genetic information in the cell line.

15 The relationship between biotechnology and bio-prospecting arise when scientists can use the genetic resources of animal or plants cell for the development of product, process, or a product by the process which is called "biological technology". One of the major uses of modern biotechnology is in genetic modification in which modern techniques of genetic enhancement are used to alter biological organisms beyond that which is attainable using natural selection and controlled breeding and makes to possible for the potential commercial value through the creation of products with desirable traits.

gains from the products/processes of the biological resources, for example, the trade of commercial seeds, which has been improving in recent years. The data from two leading international NGOs, the International Seed Trade Federation (FIS) and the International Association of Plant Breeders (ASSINSEL), show that the commercial seed market has a value of $30 billion annually[16]. In the United States, the sale of the nursery, greenhouse, and floriculture crops had increased to $10.9 billion in 1997 from $ 7.6 billion in 1992, which represents a 43 percent increase in sales on the 1992 census[17]. The nursery and greenhouse crop production now ranks among the top five agricultural commodities in 24 states and among the top 10 in 40 states in the US[18]. It should also be pointed out that the estimation of world food production in the year 2050 will need to double for an estimated world population of 11 billion, with 90 percent of the additional need arising in the developing countries. Kerry ten Kate and Sarah A. Laird have estimated that the annual world sales of products from genetic materials in the form of "pharmaceuticals, botanical medicines, major crops, horticulture, crops production, biotechnology (other than health care and agriculture) and cosmetics and personal health care sectors lie between $500 to $800 billion annually[19]. In the United States, it is thought that about 20 percent of all prescriptions are filled with drugs whose active ingredients are extracted or derived from plants[20] and in the 1980 the value of them was about US$ 4.5 billion."[21]. Sale of these plant-based drugs in the United States increased three-fold between the 1980s and 1990s.

Bio-prospecting has both positive and negative impacts. The positive impacts of bio-prospecting can be seen from the improvement of the derived products and the process such as high yield crop seed, the knowledge to society from research and development, and the revenue from selling biological resources. However, it can also be seen that bio-prospecting raises some negative impacts and unresolved issues. For

16 Graham Dutfield, Intellectual Property Rights, Trade and Biodiversity (2000) p.1

17 Hearing before the subcommittee on courts, the internet, and intellectual property of the committee on the judiciary, US. House of Representatives, *Plant Breeders Equity Act of 2002* ,September 19, 2002 p. 14

18 Hearing before the subcommittee on courts, the internet, and intellectual property of the committee on the judiciary, (n 14) p. 14

19 Kerry ten Kate and Sarah A. Laird, *The commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing*, (Earth-scan, London 1999)

20 P. Principe, *Monetizing the Pharmacological Benefits of Plants*, U.S. Environmental Protection Agency, Washington D.C. 1991

21 See World Resources Institute Website: http://www.wri.org/wri/biodiv/pharmacy.htmb (6 April 2006)

example, there are concerns about the legal issue of sovereignty of States over the issue of bio-piracy, the implications of the rise of price for biological products that mean that people in developing countries may not be able to pay for more expensive seed, and the increasing dependency of people on biotechnology.

1.3 The Problem

The problem of bio-prospecting that is the focus of this thesis occurs when people can bio-prospect the biological resources from anywhere in the world and then be able to apply for patent protection as long as they meet the criteria of patentability without having to be concerned with the issue of sovereignty of the State over biological resources. In addition, this bio-prospecting problem has now become a global problem after TRIPs's articles allow biological products/processes to be patentable throughout the members of the WTO. Many developing nations who own valuable biological resources but lack technological knowledge saw that their biological resources can be taken out from their countries without their permission, because of failure or inability of the sovereign states to control exports, and go into other countries and receive monopoly protection of the product or process as a result of limited criteria of patentability of TRIPs. So, for example, *John Robertson and Douglas C. Calhoun*[22] explaining the subject of sovereign rights of States over biological resources, pointed out that a nation's genetic resources are subject to the sovereignty of the country and therefore policy should reflect a balance between the need to conserve and develop genetic resources, the need to maintain access to international genetic resources, and the need to give States the opportunity to receive direct and indirect benefits from the genetic resources.

It should be worth to discuss briefly about the relationship between the Convention on Biological Diversity (CBD) and TRIPs [23]. Even though CBD

22 John Robertson and Douglas C.Calhoun, *Treaty on Biological Diversity: Ownership Issues and Access to Genetic Materials in New Zealand* , (European Intellectual Property Review 1995, 17 (5)),p. 219-224

23 The relationship between the TRIPs Agreement and the CBD is complicated when it comes to issue of bio-prospecting. . The Convention on Biological Diversity (CBD) was entered into force in December 1993 prior the TRIPs Agreement which was in 1994. The main objectives of the CBD are conservation of biological diversity, sustainable use of its components, and regulate fair and equitable sharing of benefits arising out of biological resources. The agreement covers all ecosystems, species, and genetic resources. With regards to problem of bio-prospecting, CBD has clearly dealt with many issues including issue of

recognize the state sovereign right to exploit their own resources[24] in which it was believe it would successfully be able to deal with the problem of bio-prospecting, however, the CBD have not made any legally impact to the problem of bio-prospecting. There have many reasons of why the CBD couldn't put forward to achieve the objective, for example, the United States believed that the CBD would undercut efforts for all countries to adopt uniform intellectual property regulations as a result of an improper transfer of technology through compulsory licenses[25], CBD[26] lacks of effective enforcement mechanism when compare to the TRIPs agreement and etc. It should be noted that the birth of the CBD[27] was part of a blueprint of

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bio-prospecting, for example, measures and incentives for the conservation and sustainable use of biological diversity, issue of regulations regarding access to genetic resources and traditional knowledge, Prior Informed Consent of the party providing resources, sharing in a fair and equitable way, research and development and the benefits arising from the commercial and other utilization of genetic resources. With Regards to the TRIPs Agreement, it aims to provide a multilateral framework for promoting effective and adequate protection of intellectual property rights both to reduce distortions and impediments to international trade and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to trade. With regards to the problem of bio-prospecting, article 7 of TRIPS states "protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations". With regards to the question of conflict between TRIPS and CBD, there are still disagreement between nations in WTO. One side considers there is no conflict between the two Agreements and member of the WTO can implement the two in a mutually supportive way through national measures are applied in a non-conflicting and mutually supportive way whereas the other side considers there is inherent conflict between the TRIPs Agreement and CBD, therefore, the TRIPs needs to be amended to remove such conflict as explained in chapter 4.

24 Principle 3: Principle of the Convention on Biological Diversity "States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction"

25 Siddhartha Parkash: WTO Rules, Do they conserve or threaten biodiversity; The Journal of World Intellectual Property Vol.3 No.1 Jan. 2000 p.158.

26 Article 11 Incentive Measures: Each Contracting Party shall, as far as possible and as appropriate, adopt economically and socially sound measures that act as incentives for the conservation and sustainable use of components of biological diversity. Article 22. Relationship with Other International Conventions: The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity.

27 Convention on Biological Diversity is the convention that see the importance of biological diversity as global asset for present and future generations. The United Nations Environment Programme (UNEP) convened the Ad Hoc Working Group of Experts on Biological Diversity in November 1988 to explore the need for an. international convention on biological diversity. In May 1989, it established the Ad Hoc Working Group of Technical and Legal Experts to prepare an international legal instrument for the conservation and sustainable use of biological diversity. The experts were to take into account "the need to share costs and benefits between developed and developing countries" as well as "ways and means to support innovation by local people". By February 1991, the Ad Hoc Working Group had become known as the Intergovernmental Negotiating Committee. Its work culminated on 22 May 1992 with the Nairobi Conference for the Adoption of the Agreed Text of the Convention on Biological

Agenda 21[28]. The objectives of the CBD are the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding[29].

As it can be seen that the problem of patent law with regards to bio-prospecting has been in discussion for years and disputes can be seen, for example, Basmati rice, the Neem tree, and Turmeric[30]. The problem of bio-prospecting comes as a result of rapid change of technology with the slow process of the political decision at the international level in order to keep itself up with the surrounding issues[31]. It can be seen that TRIPs has been imposed as an international obligation in which, so far, it has been proven to be inflexible for the developing countries to deal with various problems arisen adequately, for example, bio-prospecting problem, the problem of enforcement, and the difference between developed and developing nations when it comes to the issue of implementation. There have been numerous attempts to review and amend TRIPs agreement in order to address, for example, the problem of bio-prospecting which has been raised by the members of the WTO in

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Diversity. The Convention was opened for signature on 5 June 1992 at the United Nations Conference on Environment and Development (the Rio "Earth Summit"). It remained open for signature until 4 June 1993, by which time it had received 168 signatures. The Convention entered into force on 29 December 1993.. The CBD largely considers the issues of conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising from the use of genetic resources.

28 Agenda 21 is an action plan of the United Nations (UN) related to sustainable development and was an outcome of the United Nations Conference on Environment and Development (UNCED) held in Rio de Janeiro, Brazil, in 1992. It was a comprehensive blueprint of action to be taken globally, nationally and locally by organizations of the UN, governments, and major groups in every area in which humans directly affect the environment. The full text of Agenda 21 was revealed at the United Nations Conference on Environment and Development (Earth summit), held in Rio de Janeiro on June 13, 1992, where 178 governments voted to adopt the program. The final text was the result of drafting, consultation and negotiation, beginning in 1989 and reach the conclusion at the two-week conference. There are 40 chapters in the Agenda 21, divided into four main sections. Those are Social and Economic Dimensions section which deals with combating poverty, changing consumption patterns, promoting health, change population and sustainable settlement; Conservation and Management of Resources for Development section which includes atmospheric protection, combating deforestation, protecting fragile environments, conservation of biological diversity (biodiversity), and control of pollution; Strengthening the Role of Major Groups section which deals with Includes the roles of children and youth, women, NGOs, local authorities, business and workers; and Means of Implementation section which includes science, technology transfer, education, international institutions and financial mechanisms.

29 Article 1: objectives of CBD

30 This three cases will be explained in details in chapter three.

31 Trips Agreement/ Art 71/(http://doconline.wto.org) (2 June 2005)

numerous ministerial meetings and general councils, but they have not been successful due largely to political reasons to be discussed in Chapter 4. In addition, developed countries have strengthened IPR commitments through aggressive intellectual property protection schemes contained in bilateral agreements (sometimes known as TRIPS Plus agreements) which include trade concessions that leave no choice for poor countries but to take what the developed countries have offered.

The problem arising out of patent protection both at the domestic level and in discussion at international forums is that the IPRs in particular patents might only bring benefits to countries where their socio-economic conditions are well designed but might be a cost for other countries, particularly developing nations. So for example, there are arguments that western-style IPRs, in particular patent law, are not suitable for developing nations because of the differences of environment, level of technology, expertise, training, capital, and infrastructure to support the research based industries required for products and processes for which patent protection is needed[32].

Therefore, in order to deal with the problem of bio-prospecting, the use of patent law under the TRIPs agreement should ideally be constrained by conditions and tools designed to address the problem of bio-prospecting by recognizing the sovereignty of States over natural resources through reinterpretation or amendment of the TRIPs agreement, or through other means outside TRIPs. Although the reinterpretation of TRIPs might be an option, the interpreter must be very careful to understand the articles of TRIPs before they want to introduce anything because of the rigidity of TRIPs articles. As for an amendment, this might answer the problem of bio-prospecting because it directly addresses the problem of abuse of IPRs, however, it might also be the most difficult option because the amendment at the WTO must come in the form of consensus which will be politically difficult to achieve as can be seen from the differences expressed by Members of the TRIPs Council. This thesis will therefore propose that, in order to escape the rigidity of TRIPs articles and most importantly the political difficulties of negotiating an amendment, the conditions and tool to legally regulate the problem of bio-prospecting must be dealt with outside the scope of patent law. The conditions and tool to deal with the problem of bio-

32 Discussions have been illustrated in the Chapter 2: Literature Review

prospecting will be analysed in the context of so-called "biodiversity legislation". The new legislation will be used to address the problem of bio-prospecting equipped with the conditions in this thesis, will be the best way to escape the rigidity of the TRIPs agreement and political deadlocks and to focus on any biodiversity's issues to be arisen in any area in the near future. It should be noted that the conditions and tools to be evaluated will be Prior Informed Consent, Benefit Sharing Schemes and Social Impact Assessment, and their potential application in Thailand as an example of a developing country will be analyzed[33].

As mentioned that Thailand has been chosen as an example. It should be noted that in the last twenty years of Thailand, even though the concerns of environmental issue has visibly been seen from the development of well being of people, however, the concern of the importance of intellectual property protection regarding biological resources have not been aware because of the policy maker does not seem to aware of the importance of the biological resources under the intellectual property regime economically and socially, therefore, the problem of bio-prospecting has not been addressed. Even though, in Thailand, there are many legislations those can considerably be seen as tools to deal with the problem of bio-prospecting but none of them was designed originally and particularly for the issue of bio-prospecting. It should be briefly clarified that at the moment, there are several ministries in Thailand those can inefficiently and ineffectively use their legal tools to deal with the problem of bio-prospecting. Those are the Ministry of Interior, Ministry of Agriculture and Cooperatives, and Ministry of Natural Resources and Environment. However, the problem arises when there is no single efficient tool and single agency that particularly look after the problem of bio-prospecting. Those legislations will be explained in details in chapter 7 (7.2) of why these legal tools cannot efficiency be used with the problem of bio-prospecting. Therefore, this thesis will be written to address the problem of bio-prospecting and the reasons of why there should be a recommendation made in this thesis regarding the problem of bio-prospecting in Thailand[34].

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33 PIC, BS and SIA are conditions and a tool those recognize sovereign rights of state and require consent of any activities prior the use of biological resources.

34 There are several ministries in Thailand have legal tools to deal with the problem of bio-prospecting as can be explained as follows: The first one is the Department of Land (DOL), Ministry of Interior (MOI). Under the MOI, the main responsibility is

1.4: Organization of the thesis

This thesis will be divided into ten chapters.

The first chapter is an introduction which states the purpose of the study, background of the study, the problem to be addressed, and the approach of the thesis to the question of how Thailand could legally deal with the problem of bio-prospecting. The second chapter is a literature review. The literature review will

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to issue of land deed. There are different types of land title deed in Thailand. Those are as follows: 1. Chanot (Nor Sor 4): This type of title deed, registered at the Land Department in the province in which the land is located, grants the holder of the documents full rights over the land. It is therefore the strongest type of title deed. The title deed contains a legal description of the land boundary markers that are carefully ascertained and referenced by satellite images. 2. Nor Sor 3 Gor: This land title designates ownership of land with fairly certain boundaries, however it is not yet a full land title (chanot). A final official measuring is required by the land department along with the placing of official markers. This type of land title may be sold, transferred, or mortgaged. If the owner of the land files a request with the Land Department, surveyors from the land department will measure the land, the title may be changed to Chanot. 3. Nor Sor 3: Although ownership of the land covered in this title is relatively ascertained, the Land Department has never measured or recognized the boundaries. Therefore boundary markers are normally placed by property owners rather than government authorities. Accordingly, the main risk is whether the boundaries and size of the land is accurate. 4. Possessory Right: This is normally an inherited land right proven by tax payments at the local administrative office. It is one of the weakest types of land rights. 5. Sor Por Kor 4-01: This is an agricultural title deed, usually found in rural areas. Government land is transferred for agricultural purposes to needy families. Residence is allowed on a portion of the land. It is difficult for a non-Thai to obtain an interest in this type of land deed. For the second agency, it is the Ministry of Agriculture and Cooperatives (MOAC). With regards to the problem of bio-prospecting, MOAC is responsible for two Acts. Those are Plants Act B.E. 2518 (1975) and Plant Variety Protection Act. One of the objectives of Plants Act was written to prohibit the collection, sell, importation, exportation, or carry across plant, controlled plant/ seed, prohibited plant/seed, registered varieties/seed, and reserved plant/seed without permission. The other act is Plant Varieties Protection Act B.E. 2542 (1999). Since Thailand is not member of UPOV, therefore, Thailand has chosen to write her own law with regards to plant variety protection or so called sui generis system in order to be conformed to the TRIPs agreement. For the third agency is the Ministry of Natural Resources and Environment (MNRE). For the problem of bio-prospecting, MNRE is responsible for seven Acts. The first six Acts are the National Reserved Forest Act of 1964, the National Park Act of 1961, the Forest Act of 1941, the Wild Animal Reservation and Protection Act of 1992, the Fishery Act of 1947, the Animal Variety Promotion Act of 1966. All of these six legislations have indicated that the use of biological materials obtained from protected areas in the legislations shall receive permission first before using it both for the commercial and non-commercial use since the MNRE is responsible for the reserved areas in Thailand. In addition, for the Wild Animal Reservation and Protection Act was written for the protection of the protected and wild life animal in the protected area in which prohibit people to hunt, keep, import, and export the entire wild life animal as listed in the annex without permission. The Wild Life Act was promulgated for the CITES convention. The last Ministry is Department of Intellectual Property Protection (DIPP), Ministry of Commerce(MOC), With regards to the problem of bio-prospecting, DIPP is responsible for the Patent Act B.E. 2522 (1979) as amended by the Patent Act (No.2) B.E 2535 (1992) and the Patent Act (No.3) B.E. 2542 (1999). The Patent Act was promulgated for TRIPS Agreement.

address how the problem of bio-prospecting has been academically discussed. The third chapter discusses the general principles of current intellectual property rights, in particular patent law. This chapter focuses largely on the key jurisdictions of the European Union and the US, in order to illustrate how patent law has been developed and interpreted, including patentability of live forms, criteria, eligibility, exclusions, and relevant legal instruments. The purpose is to evaluate how the criteria of patentability are a problem when dealing with bio-prospecting, and three examples of problems arising out of the patent law and bio-prospecting will be given as illustrations. Chapter 4 will be a legal critique of the TRIPs agreement. In order to answer the research question of how Thailand can legally deal with the problem of bio-prospecting, it is necessary to examine the TRIPs agreement to see its effects, and whether the text can be reinterpreted or amended. It should be noted that the TRIPs agreement is central to an analysis of the IPR aspects of bio-prospecting because it is the most important international agreement with regards to the patent law, due to its enforcement mechanism and the large number of countries that are parties to the TRIPs agreement (currently 153 States as of 2008). Chapter 5 then examines the conditions of patentability and access to biological resources that may ensure that the rights of the innovator and the rights of developing countries are in balance with regards to the bio-prospecting. These conditions are Prior Informed Consent (PIC) and benefit sharing schemes (BS). Chapter 6 introduces a potential tool to justify the application of the formal conditions suggested in Chapter 5. This tool is called Social Impact Assessment (SIA). It should be noted that the reason why this thesis has chosen to recommend the SIA as a desirable tool is because it can be used to calculate quantitatively and qualitatively the benefit and cost of using the conditions. In other words, it provides a rationale for permitting bio-prospecting and a method of assessing and quantifying the benefit arising out of granting access and utilization of biological resources. Chapter 7 reviews biodiversity legislation as a possible option to address the bio-prospecting problem under the rule of TRIPs. It will examine how biodiversity laws have been written in different countries or regions, including their strengths and weaknesses. Chapter 8 applies the preceding analysis in a factual context by examining the bio-prospecting problem in Thailand, a developing country which possesses abundant biodiversity and is a Member of the WTO. Chapter 8 also recommends how Thailand could deal with the problem of bio-prospecting. Chapter

9 is summary chapter. It draws together the analysis and offers conclusions of each chapter. Chapter 10 is recommendation chapter. It draws various recommendations made during the thesis and explains on how Thailand can legally deal with the problem of bio-prospecting. Chapter 11 is the bibliography.

Chapter 2: The Literature Review

There are many aspects to the problem of bio-prospecting such as the conservation, sustainable development, the bio-prospecting and IPRs. The problem of bio-prospecting addressed in this thesis is the unsettled issue between the issues of sovereign rights of states over biological resources and the patent law. The problem of bio-prospecting and the patent law has been greatly discussed in the literature in the past few years especially after the TRIPs agreement came to force. The reason is because the TRIPs agreement allows its member countries to give the exclusive rights to the biological products/ and process without recognizing the sovereign rights of states over biological resources. Many academics, NGOs, and some members of the WTO have questioned the legitimacy of the TRIPs agreement since the sovereign rights of state over her biological resources has now been recognized internationally through the Convention on Biological Diversity, however, the article of the TRIPs agreement with regards to the problem of bio-prospecting has not been changed, therefore, the patent law can still take away the public property to private property without receiving any permission and sharing the benefit arising out of the utilization of the biological resources. Many academics, NGOs, and governments argue that the patent law should not be allowed to take away the public ownership of biological resources to a private ownership or TRIPs should at least recognize the sovereign rights of states when patentee wants to patent the product/ process that use the biological resources which belong to a particular country. The current status of the research has partly been identified by many researchers such as Peter Drahos, Michael Blankeney, Thomas Cottier, Graham Dutfield, Carlos Correa, but it is not comprehensive. This thesis sees that the main problem that this thesis found is the rigidity of the articles of the TRIPs agreement which seem not to allow member of the WTO agreement to introduce any mechanisms to deal with the problem of bio-prospecting. Problem identification which has recognized the sovereign rights of the country over their natural resources as can be seen from the ratification of the Convention on Biological Diversity and some mechanisms through the Bonn guidelines have been identified, however, the research still need to find out on how to put those mechanisms into places and where it can be put on without violating the TRIPs agreement and is there any other mechanism that we can introduce in order to

justify the grant of patent protection. The following articles and books will give a reader an idea that the problem of bio-prospecting and patent law has largely been discussed and some of the recommendation in the articles and journals has also been used in this thesis. The following books and articles are examples of what people had been written about the TRIPs agreement.

With regards to the bio-prospecting problem and patent law, there are articles and books looked at the suitability and implications of it to the people as can be seen as follows: The first book by *Correa, C.M. Yusuf*, *and A.A.* Eds. (1998), Intellectual Property and International Trade: The TRIPs agreement[35], this book explained what the TRIPs is. It also discussed about the growing issues to international law and international economic relations in respect of the possibilities offered by TRIPs. The second book also by *Correa, C.M.* "Intellectual Property Rights, the WTO and Developing Countries: The TRIPs Agreement and Policy Options" This book explores the implications of TRIPs to the member countries in particular developing nations in the areas of information technologies, integrated circuits, and also the conservation and sustainable use of genetic resources for food and agriculture. The third one is an article[36] by *Bhat, M.G*. which looked at the imperfection of TRIPs agreement. This paper saw the TRIPs might provide enough incentives for the innovator for the production of high yielding seeds, bio-pesticides, and fertilizers but in the longtime the survival, sustainable use, and benefit arising out of the utilization of biological resources for biological prospecting and conservation needs to be redesigned. The book from *Gaia Foundation and Genetic Resources Action International* "TRIPs versus CBD: conflicts between the WTO regime of intellectual property rights and sustainable biodiversity management"[37] It tried to point out that there is a conflict of the objectives between the TRIPs and the CBD. It tried to explain the CBD should have a primacy over the TRIPs with regards to traditional knowledge and the rights to use biological resources. The book by *Dutfield G*: "Can

35 Correa, C.M. and A.A. Yusuf, Eds. (1998), Intellectual Property and International Trade: The TRIPs agreement. London, the Heague and Boston, Kluwer Law International.

36 Bhat, M.G. (1996). "Trade-related Intellectual property Rights to biological resources: Socioeconomic implications for developing countries." Ecological Economics 19: p. 205-17

37 Gaia Foundation and Genetic Resources Action International (1998) "TRIPs versus CBD: conflicts between the WTO regime of intellectual property rights and sustainable biodiversity management". Global Trade and Biodiversity in Conflict, Issue 1, London& Barcelona, Gaia Foundation and GRAIN.

the TRIPs Agreement protect biological and cultural diversity?"[38] The author had criticized that even though the TRIPs agreement is fully justified, however, the TRIPs agreement still does not cover all the issues those relate to the IPRs such as the issue of human rights, traditional knowledge, and biodiversity-related aspects of IPRs. The book has pointed out ways and means to bridge the gaps between the IPRs and the other issues.

With regards to the importance of biological resources, there have been a lot of discussions about the importance of biological resources in terms of social benefit and economic benefits. The first book called "Biodiversity: New Leads for the Pharmaceutical and Agrochemical Industries"[39] indicating the importance of biological resources including the marine organism for the production of new drugs and agrochemicals products. This book shows that microbial, plant and marine products are new sources of new drugs, antibiotics, anti-cancer agents, and animal health products. The other book called Good Practices and Innovative Experiences in the South[40] pointed out in the chapter 5 that the importance of plants for the medical use. This chapter pointed out that the traditional practices of herbal plants has long been used for many peoples and the lists of plant have been published worldwide and there have been a lot of economic activities relating to the growing of herbal plant. Similarly to the book by *Crucible Group* "People, Plants and Patents: The impact of Intellectual Property on Trade, Plant Biodiversity, and Rural society"[41] It discussed the importance and the implication between the IPRs and biological diversity in particular plant on the implications for food securities, agriculture, and multi-functionalities. The article by *David Ehrendeld*[42], "Why put a Value on Biodiversity?" also pointed out the importance of plants and animals for the pharmaceutical industry in terms of economic benefits and for the scientific

38 Dutfield G. (1997), "Can the TRIPs Agreement protect biological and cultural diversity?" Bio-policy International No. 19. Nairobi, African Centre for Technology Studies.

39 S.K. Wrigley, M.A. Hayes, R. Thomas, E.J.T. Chrystal and N. Nicholson; Biodiversity: New Leads for the Pharmaceutical and Agrochemical Industries, Royal Society of Chemistry

40 Martin Khor and Lim Li Lin; Good Practices and Innovative Experinces in the South: Social Policies, Indigenous Knowledge and Appropriate Technology; Third World Network Volume 2

41 Crucible Group (1994). People, Plants and Patents: The impact of Intellectual Property on Trade, Plant Biodiversity, and Rural society. Ottawa, International Development Research Centre.

42 David Ehrendeld, "Why put a value on biodiversity"; Chapter 24 p. 212- 216

community. The other article in the book by *Benjamin Gilbert* called "Brazilian Biodiversity: A Source of Phyto-medicines, natural drugs and leads for the pharmaceutical and agrochemical industries" which discuss about the biodiversity of Brazil where it is a major sources such as plants and biological compounds of new pharmaceutical and agro-chemical leads and pointed out the traditional medicines and lists of valuable plants for the pharmaceutical industries. Michael Blankeney also wrote an article[43] about the bio-prospecting and the protection of traditional knowledge examines the IP law in Australia whether it can protect the indigenous knowledge. The author pointed out that Australia has some 44,000 species of plants of which 90 percent occur only in Australia and indigenous people know which plants can be used for medicines. These plants can make considerable amount of money to the researchers and pharmaceutical companies; however, the contribution of the indigenous people has not properly been rewarded. Even though the author pointed out that there has been a lot of recognition through the declarations and in the agreements which recognize the importance of biological diversity (The Inter-governmental Agreement on the Environment (IGAE), however, all these agreements still do not legally recognize the contribution of the indigenous people when it applies for the IP law in particular the patent. And article by *Thomas Cottier*, "The Protection of Genetic Resources and Traditional Knowledge: Towards more specific rights and obligations in world trade law[44]": this article looks at IPRs issues relevant to the exploitation of genetic and biological resources.

With regards to the pro and Con of granting of patent protection over the biological resources, there are important literatures in favour and disfavour the grant of patent protection over the biological resources. For the book and articles in favour of patent law and bio-prospecting can be seen as follows:

The first article by Dutfield and Posey, they favoured the patent law because they believe that the market mechanism will allow people to share benefit in the long run. They wrote that many people believe that a market-based approach in this case

43 Michael Blakeney: Bio-prospecting and the Protection of Traditional Medical Knowledge of Indigenous Peoples: An Australian Perspective; European Intellectual Property Review 1997, 19 (6) p.298-303

44 Thomas Cottier, The Protection of Genetic Resources and Traditional Knowledge: Towards more specific rights and obligations in world trade law, Journal of International Economic Law (1998) p. 555-584 Oxford University Press.

would be the IPRs scheme will promote equity because it allows local people to share the benefits derived from the use of biological resources as referred to a bio-prospecting.[45] In favour of IPRs, Gollin also supported the IPRs that the IPRs are a mean to strengthen biodiversity conservation efforts. He cites a number of studies to prove that many counties receive a minimum level of technology in which they reach a threshold where the IPR is an important tool to protect exported product and facilitate the technology transfer as can be seen from the study of the World Bank shows that the leading pharmaceutical companies do not conduct research in countries with weak IPRs and vice versa[46]. Other theory of the IPRs were found that the rational of introducing the patent protection is to balance the rights of inventors to derive benefits from their inventions and the rights of the public to have access to novel ideas[47]. The prior sentence can also be seen from the following sentence which describes the characteristic of the TRIPs agreement that as it recognized in its preamble that the intellectual property right is a private right, therefore, many developed nations believe that a high level of intellectual property protection is necessary to encourage innovation and development and therefore, a higher level of IPRs is a prerequisite for LDCs to attract foreign direct investments and transfer of technology[48]. This has been supported by the studies by the World Bank that the leading pharmaceutical companies do not want to conduct research in countries with a weak IPR[49], therefore, many critics such as Redwood saw that the impact of the IPRs on developing countries would be of benefit from the foreign direct investment and the stimulation of R&D if the developing nations implement the TRIPs agreement[50]. The other argument in favour of applying an IPR to biodiversity strategy is as follows:

45 Posey, D., and G. Dutfield, 1996: Beyond Intellectual Property: Toward Traditional Resource Rights for Indigenous Peoples and Local Communities, International Development Research Council (IDRC), Ottawa.

46 Gollin, M., 1993: An Intellectual Property Rights Framework for Biodiversity Prospecting, in Biodiversity Prospecting, World Resources Institutee, D.C.

47 David F. Sheppard; Patent Law in South Africa with Particular Reference to the TRIPs Agreement; the Journal of World Intellectual Property Vol. 2 No.4 July 1999 p. 619

48 Olivier Cattaneo; the Interpretation of the TRIPs Agreement: Considerations for the WTO Panel and Appellate Body; the Journal of World Intellectual Property vol.3 No.5 September 2000 p.631

49 Siddhartha Prakash, Towards a Synergy between Biodiversity and Intellectual Property Rights; The Journal of World Intellectual Property Vol. 2 No.5 September 1999 p.823

50 Redwood, H., 1994: New Horizons in India, Oldwicks Press, Suffolk

"…if those who control a habitat hold proprietary rights to develop its biological resources, then they have a means for obtaining economic benefits from those resources, and consequently, an incentive to conserve rather than destroy them"[51] .

However, there are also arguments against the IPRs with regards to the bio-prospecting. The first arguments made with regards to the right of the people who normally live and own the biodiversity in which it contradicts with the concept of IPRs which transfer the public rights to private right as can be seen that most of the third world communities meet their basic needs through biodiversity and indigenous knowledge, knowledge of breeding of nutrition and medicinal plants, therefore, biodiversity and indigenous knowledge are centred on human rights and the economic security of people[52]. Other concerns can be seen that one of the concerns of patenting live forms in the developing nations would be that such form of protection would infringe on traditional farming practices[53]. There are also a lot of critics argue that IPRS are a threat to biodiversity because they limit access to resources and production derived from it[54]. In supporting the prior sentence, Tonye wrote in the article that the public ownership of the biological resources shall be determined through the change of law of self-determination in order to address the problem of bio-prospecting that the concepts of territorial rights and self-determination of rural communities have not been built into many laws which mean that addressing land ownerships/ territorial rights and self-determination appears to be a step forward that biodiversity-rich countries are expected to make themselves in the sense of giving the communities the rights over the land where these resources are exploited and the right to determine who can have access and how this should be done[55]. The other reason can be understood that the patent regime should not be an appropriate place for the biological resource such as for the plant varieties protection because a profit making enterprise from the patent protection is linked to traditional agricultural practices of seed saving

51 Gollin, M., 1993: An Intellectual Property Rights Framework for Biodiversity Prospecting, in Biodiversity Prospecting, World Resources Institute, Washington, D.C.

52 Vandana Shiva; TRIPs, Human Rights and the Public Domain; The Journal of World Intellectual Property . Vol.7 No.5 September 2004 p. 667

53 Siddhartha Parkash: WTO Rules, Do they conserve or threaten biodiversity; The Journal of World Intellectual Property Vol.3 No.1 Jan. 2000 p.159

54 Siddhartha Prakash, Towards a Synergy between Biodiversity and Intellectual Property Rights; The Journal of World Intellectual Property Vol. 2 No.5 September 1999 p.822

55 Marcelin M. Tonye, Thai PVP/Sui Generis Systems for the Legal Protection of Traditional Knowledge and Biogenetic Resources in Cameroon and South Africa; the Journal of World Intellectual Property, Vol.6 No.5 September 2003 p. 773

and exchange and to the perception that the fulfilment of food needs[56]. One of the best example which regards to the cost of IPRs can be explained by the American College of Medical Genetics has recognized that patents are a block to cures: "Monopolistic licensing that limits a given genetic test to a single laboratory, royalty-based licensing agreements with exorbitant up-front fees and pre-test fees, and licensing agreements that seek proportions of reimbursement from testing services. These limit the accessibility of competitively priced genetic testing services and hinder test-specific development of national programs for quality assurance."[57] In addition, there has been a lot of discussion between the improvement of protecting modern invention and the realization of property rights to genetic resources. The below discussion can be seen as follows:

> "There is currently still relatively little interest on the part of developed countries and industry to undertake or even press for conceptual work on Farmers' Rights or comparable approaches of allocated property rights to natural genetic resources. Developed countries and their industries, however, should realize that conceptual work on revaluing natural resources is an essential ingredient to achieve fruitful cooperation in situ which often is necessary for successful research. Moreover, they should note that such work is necessary to further political progress in protecting globally their own value-added products in particular in developing countries. It is likely that attitudes of less developed countries toward the advancement of protection of inventions related to biotechnology and genetic engineering will depend on progress in the field of protecting traditional resources. In my view, both areas need parallel development in the international forum and law. Progress can only be achieved if the equities are balanced. Both, the giving and receiving ends, need legal titles as a basis for cooperation. Without the equation, it is likely that progress in the global protection of inventions related to modern biotechnology will be much more difficult to achieve. Absence of adequate property rights granted to traditional genetically resources amounts to a powerful argument against the patenting of life form……"[58]

56 Commission on Genetic Resources for Food and Agriculture, Possible Formulas for the Sharing of Benefits Based on Different Benefit-Indicators, Rome, 8th Sess., 19-23 April 1999, Doc. CGRFA-8/99/8

57 American College of Medical Genetics, Position Statement on Gene Patents and Accessibility of Gene Testing, available at "www.faseb.org/genetics/acmg/pol-34.htm) (5 July 2004)

58 Cottier, Thomas, 1995b: The protection of Intellectual property Rights: A Requirement of Technology Cooperation. Foreign Investment and Equitable Returns in Biotechnology Prospecting, in Biotechnologies Fur Entwicklungslander: Chancen und Risiken Der Biotechnolgie bei Landwirtschaftlichen Nutzpflanzen p.65

It should be noted that in the 2000 Report of the UN Human Rights Commission on "Intellectual Property Rights and Human Rights" has described the WTO a "veritable nightmare" for developing countries and LDCs from the perspective of the full enjoyment of economic, social and cultural rights[59]. Because of that the developing nations see the intellectual property is a public good, belonging to the "common heritage of mankind" and should be shared without compensation[60]. One of the reasons is that the LDCs believe that an effective IPRs scheme would cost them more than the benefit that they would anticipate from this discipline[61] and would impede their economic development[62]. As a consequence, bio-prospecting for substances which have useful for medicinal products and R&D to produce new varieties of plants have increased in the last decade in which it has create conflicts both domestically and internationally between different actors since the knowledge used by the large companies to manufacture patented products cannot be equated with a discovery, therefore, bio-prospectors often rely largely on local people with special knowledge of plants found in their localities to identify potential useful plants[63]. This can also be supported by the article 12 of the Berne Convention on the Protection of Literary and Artistic Works (1971) which is an Agreement recognized by the WTO, confirms that the owner of the artistic work enjoys the exclusive rights of authorizing adaptations and alterations to the original work. A parallel could be drawn with the modification and changes made to materials under the Multilateral System or genetic resources that are the sovereign rights of countries[64]. In addition, as of today,

59 The UN Commission on Human Rights, Sub-Commission for the Promotion and Protection of Human Rights, 52nd Session, Agenda Item 4, The Realization of Economic, Social and Cultural Rights: Globalization and its Impact on the Full Enjoyment of human Rights, by jurists Oloka-Onyango and Deepika Udagama, E/CN.4/Sub.2/2000/13, 15 June 2000;R.Evans, UN Report Calls WTO Nightmare, Reuter, 11 August 2000, at 1; P.Ala'I, A Human Rights Critique of the WTO: Some Preliminary Observations, 33 George Washington I.L. Rev., 2001, p. 537

60 J.A. Greenwald, The Protection of Intellectual Property Rights in the GATT and the Uruguay Round: The U.S. Viewpoint, in M.L. Jones and S.J. Rubin (eds.), Conflict and Resolution in U.S.-EC Trade Relations at the Opening of the Uruguay Round, Oceana Publications, New York, 1989, at 238-239; J.C. Ross and J.A. Wasserman, Trade Related Aspects of Intellectual Property Rights, Kluwer Law and Taxation Publishers, Deventer, 1993 p. 11.

61 T.Cottier, The Prospects for Intellectual Property in GATT, 28 Common Market Law Review 383, 1991 p. 284

62 M.C.E.J Bronckers, The Impact of TRIPs: Intellectual Property Protection in Developing Countries, 31 Common Market Law Review 1245, 1994 p. 1247

63 David F. Sheppard, Patent Law in South Africa with Particular Reference to the TRIPs Agreement, the Journal of World Intellectual Property, Vol.2 No.4 July 1999, p. 630

international law characterizes and recognizes the genetic resources as being subject to the sovereignty of States and endows the States with the power to determine legal status of genetic resources within their jurisdictions[65]. This has been supported from the paper by *Baxter, B., S. Mayer and A. Wijeratana* (1999), "Crops and Robbers: Bio-piracy and the Patenting of Staple Food Crops: Preliminary Findings of an Action Aid Investigation" London, Action Aid shows the IPRs scheme and the genetic engineering has let to the change of public ownership to private ownership in particular private companies which led to a higher prices of patented seeds and royalties in which directly hurt the poor people in the south.

In addition, there are many academics wrote articles against the grant of patent protection on biological resources. Grant E. Isaac and William A. Kerr wrote an article[66] discussed about the differences between the discovery and invention through bio-piracy for the intellectual property protection. The article carefully examined and point out the differences and benefit and costs of giving IPRs to the products and process that results of the discovery. The article would like to see the IP systems would not grant a patent protection to what a traditional discoveries has been acquired through bio-piracy. *Elizabeth Henderson* affirmed the implication of patent law under the TRIPs agreement in the article called "TRIPs and the Third World: The Example of Pharmaceutical Patents in India[67]" pointing out that the western style IPRs in particular patent law were not suitable to the developing nations because of the differences of the environment, level of technology, expertise, training, capital, infrastructure to support the research based industries where the developing nations does not have in which the product and process that to receive the patent protection is needed. *Jakob Cornides* also criticized the IPRs from human rights perspective in the

64 W. Bradnee Chambers, Emerging International Rules on the Commercialization of Genetic Resources: The FAO International Plant Genetic Treaty and CBD Bonn Guidelines; Journal of World Intellectual Property Vol. 6 No.2 March 2003 p. 324

65 Martin A. Girsberger; The Protection of Traditional Plant Genetic Resources for Food and Agriculture and the Related Know-How by Intellectual Property Rights in International Law-The Current Legal Environment; The Journal of World Intellectual Property Vol. 1 No. 6 November 1998 p. 1020

66 Grant E.Isaac and William A. Kerr; Bio-prospecting or Bio-piracy?: Intellectual Property and Traditional Knowledge in biotechnology Innovation; Journal of World Intellectual Property p. 35-51

67 Elizabeth Henderson, " TRIPS and the Third World: The Example of Pharmaceutical Patents in India, European Intellectual Property Review 1997, 19 (11), p. 651-663

article[68] called "Human Rights and Intellectual property: Conflict or Convergence? pointing out the correlation between the IPRs and the Human Rights issue. The author saw the human rights and the IPRs in particular patent law are imbalance. It can be seen from many problems arising out of the IPRs in which the basic of human rights including a new and emerging concept of human rights such as right to development, right to food and etc has not been met. The paper concluded that the IPRs is still necessary for the scientific progress, however, it should strike by balancing the human rights and IPRs through the social optimization, in the other words, the article suggested that the benefit of IPRs should not only give to a few members of the society whereas a majority remains excluded from the benefits. The similar argument can be seen in the article by *Gana, R.L.* "The myth of development, the progress of rights: human rights to intellectual property and development[69]" This article tried to explain that recognizing of IPRs in the Universal Declaration of Human Rights through the western style of IPRs might not be of great benefit to the developing nations as it can be seen from, for example, Africa, therefore, the author argues that the human right to IPRs should be recognized with the context of right to development and self-determination in order to establish the IPRs regimes which reflect the socio-economic and cultural norms of the developing nations.

Bio-prospecting and sovereign rights of states over biological resources:

The Article of *John Robertson and Douglas C. Calhoun*, Treaty on Biological Diversity: Ownership Issues and Access to Genetic Materials in New Zealand[70] started with the subject of sovereign rights of states over biological resources by pointing out that the nation's genetic resources are subject to the sovereignty of the country and therefore, the policy should reflect a balance between the need to conserve and develop the genetic resources and the need to maintain access to international genetic resources and the country shall have an opportunity to receive direct and indirect benefits from the genetic resources. The prior sentence has been

68 Jakob Cornides; Human Rights and Intellectual Property: Conflict or Convergence?: Journal of World Intellectual Property, p. 135-167

69 Gana, R.L. (1996). "The myth of development, the progress of rights: human rights to intellectual property and development." Law and Policy 18 (3&4): p. 315-354

70 John Robertson and Douglas C.Calhoun, Treaty on Biological Diversity: Ownership Issues and Access to Genetic Materials in New Zealand, European Intellectual Property Review 1995, 17 (5), p. 219-224

supported by the book by *Correa, C.M.* (1994) "Sovereign and Property Rights over Plant Genetic Resources"[71] This book discussed the relationship between the IPRs over plant genetic resources and the concept of sovereign rights in particularly in the context of IUPGR and the CBD. Similarly to the book by *Frisvold, G.B. and P.T. Condon* "The Convention on Biological Diversity and agriculture: implications and unresolved debates"[72] which addressed two issues surrounding the IPRs and CBD. The first issue is the issue of property rights of the plant genetic resources and benefit arising out of it. The second issue is the measurement of maintaining genetic diversity. This has also been supported by *Christopher Heath and Sabine Weidlich* wrote an article called "Intellectual Property: Suitable for Protecting Traditional Medicine[73] discussing the right of the owner of the traditional medicine on the self determination of conservation and exploitation when it applies for the patent protection in which the author saw the importance of self determination and ownership of their property when it comes to exploitation in particular the commercial exploitation. The book by *Duessing, J. H.* "The role of intellectual property rights in the exploitation of plant genetic resources and for technology transfer under the Convention on Biological Diversity" Valuing Local Knowledge: Indigenous Peoples and Intellectual Property Rights[74] gave a different view on the issue of sovereign rights over biological resources and property rights. This book said that national sovereignty is now a kind of property rights but it does not adequately protect biological resources once it leaves the legal domain or control of a culture, therefore, it believes that standardized international IPRs with acceptance of national sovereignty over genetic resources points to a solution.

71 Correa, C.M. (1994) "Sovereign and Property Rights over Plant Genetic Resources": Commission on Plant Genetic Resources Background Study Paper No.2 Rome, FAO.

72 Frisvold, G.B. and P.T. Condon (1998) "The Convention on Biological Diversity and agriculture: implications and unresolved debates" World Development 26(4): p. 551-570.

73 Christopher Heath and Sabine Weidlich; Intellectual Property: Suitable for Protecting Traditional Medicine, Intellectual Property Quarterly 2003

74 Duessing, J. H. (1996) " The role of intellectual property rights in the exploitation of plant genetic resources and for technology transfer under the Convention on Biological Diversity". Valuing Local Knowledge: Indigenous Peoples and Intellectual Property Rights. S.B. Brush and D. Stabinsky, Covelo, CA. Island Press.

Mechanisms

There have been a lot of articles and journals discussed how the patent law under TRIPs can recognize the sovereign of states over biological resources through the mechanisms as can be seen from the following articles and books: The book by *Johnston, S. and F. Yamin* (1997), "Intellectual Property rights and access to genetic resources: Access to Genetic Resources: Strategies for Sharing Benefits[75]" It discussed the IPRs in the context of CBDs which can address the problem of bio-prospecting raised by the developing nations. Or the book by *Hoagland, K.E. and A.Y. Rossman* "Global Genetic Resources: Access, Ownership, and Intellectual Property Rights[76]" this book presented a collection of papers from a conference which show the issues of bio-prospecting with regards to the ownerships of and access to genetic resources and equitable benefit sharing. The *Australian government* has given the importance of the issue of sovereign rights over their natural resources in particular biological resources; therefore, she had released a paper in 1998 on the issue of access to Australia's biological resources[77] for the public discussion and comment. This paper discussed ways and how the biological resources in Australia could be managed and suggest the mechanism to govern access and the benefit sharing arising from the use of the biological resources. In addition "*A report of the Commission on Intellectual Property Rights*[78]" discussed about today prospect of IPRs. One of the tasks of the commission was to consider how national IPR regimes could best be designed to benefit developing countries within the context of international agreements (TRIPs) and how the international framework of rules and agreements might be improved and developed for instance in the area of traditional knowledge- and the relationship between IPR rules and regimes covering access to genetic resources. With regards to the bio-prospecting problem, the commission found that it would be fair to every country if the country would require disclosing in

75 Johnston, S. and F. Yamin (1997), "Intellectual Property rights and access to genetic resources" Access to Genetic Resources: Strategies for Sharing Benefits. J. Mugabe, C.V. Barber, G. Henne, L. Glowka and A. La Vina, Nairobi, ACTS Press: p. 245-269

76 Hoagland, K.E. and A.Y. Rossman, Eds (1997), Global Genetic Resources: Access, Ownership, and Intellectual Property Rights. Washington DC, Association of Systematic Collections.

77 Natalie Stoianoff: Access to Australia's biological resources and technology transfer, European Intellectual property Review, 1998, 20(8), p. 298-305

78 Commission on Intellectual Property Rights: Integrating Intellectual Property Rights and Development Policy, September 2002

the patent applications. The commission found that by saying "Indeed we would go further in supporting the objectives of the CBD by arguing that no person should be able to benefit from any IP rights consisting of, or based on, genetic resources or associated knowledge obtained in an illegal manner, or used in an unauthorized way."[79] The commission has been supported from the book by *Tobin, B.*, "Certificates of origin: a role for IPR regimes in securing prior informed consent: Access to Genetic Resources: Strategies for Sharing Benefits"[80] This book tried to give an alternative approach for Prior informed consent by introducing a multilateral certificates of origin system in which this paper believe to be better than an access/ benefit sharing regime which might diminish interest of bio-prospector and inventor. The book by *Secretariat of the Convention on Biological Diversity*, called "The impact of intellectual property rights systems on the conservation and sustainable use of biological diversity and on the equitable sharing of benefits form its use: a preliminary study"[81] also reviewed the impacts of the IPRs on the conservation and sustainable use of biodiversity and on the equitable sharing of benefits from its use. The other one also came from *Dutfield G*. "Sharing the benefits of biodiversity: access regimes and intellectual property rights[82]" It had explained that there are two types of regimes which regulate the use of IPR on biological resources. Those regimes are the control of access and the benefit sharing scheme. Even though it had pointed out that the IPRs in particular patent and PBRs would still good for the biological product and process but inflexibility of the global IPRs has let to the difficulty of the developing nations to be of benefit from it. The other book by *Lesser* "Sustainable Use of Genetic Resources under the Convention on Biological Diversity: Exploring Access

79 Commission on Intellectual Property Rights: Integrating Intellectual Property Rights and Development Policy, September 2002 ch. 4 p. 87

80 Tobin, B. (1997), Certificates of origin: a role for IPR regimes in securing prior informed consent", Access to Genetic Resources: Strategies for Sharing Benefits. J. Mugabe, C.V. Barber, G. Henne, L. Glowka and A. La Vina, Nairobi, ACTS Press p. 329-340

81 Secretariat of the Convention on Biological Diversity (1996), The impact of intellectual property rights systems on the conservation and sustainable use of biological diversity and on the equitable sharing of benefits from its use: a preliminary study; Note by the Executive Secretary for the Conference of the Parties to the Convention on Biological Diversity, Third Meeting. Buenos Aires, Argentina. 4 to 15 November 1996. Item 14.2 of the provisional Agenda, Montreal, and CBD Secretariat.

82 Dutfield G. (1999). Sharing the benefits of biodiversity: access regimes and intellectual property rights Science, Technology and Development Discussion Paper No.6. Cambridge, Centre for International Development and Belfer Centre for Science and International Affairs, Harvard University.

and Benefit Sharing Issues[83]" This book presented that there is some limitations for the progress of applying the CBD as the country can act unilaterally on the placement of genetic resources as their sovereign right to exploit. The other book also came by *Dutfield G*. "Intellectual Property Rights, Trade and Biodiversity: Seeds and Plant Varieties[84]" This book had pointed out the importance of the biological resources for the pharmaceutical industry and the IPRs in particular the patent and PBRs for the product and process. This book had made several points on the other international agreements such as CBD of how to integrate the IPRs and the CBD by taking into account of ethical concerns, environmental and social impacts, and etc. *Tshimanga Kongolo* wrote an article in 2002 called "Biodiversity and African Countries"[85] discussing the importance of the country to control the access of biological/ genetic resources based on the prior informed consent and benefit sharing arising out of the exploitation of the resources. In addition, the article also suggested that the African countries should try to find a mechanism to assist the community to gain from the utilization of their resources by the third party. *Martine De Koning* also wrote an article called "Biodiversity Prospecting and the Equitable Remuneration of Ethno-biological Knowledge: Reconciling Industry and Indigenous Interests[86] suggested that the bio-prospector would be required a prior informed consent and share equitable remuneration of the knowledge of indigenous people who develop the commercially drugs and pharmaceuticals. *The Columbia University* published a paper[87] examining the existing and ongoing work in the field in regulating the access to genetic resources, the benefit sharing and etc on a number of specific cases. The study came out with many valuable comments, however, they agreed that the country who owns the genetic resources must receive a PIC before the GR is to be obtained and the benefit sharing must be rewarded before and after they are taken for R&D and

83 Lesser, W. (1998) Sustainable Use of Genetic Resources under the Convention on Biological Diversity: Exploring Access and Benefit Sharing Issues. Wallingford, CAB,

84 Dutfield G. (2000), Intellectual Property Rights, Trade and Biodiversity: Seeds and Plant Varieties. London, Earthscan and IUCN.

85 Tshimanga Kongolo; Biodiversity and African Countries, European Intellectual Property Review 2002 , 24(12), p. 579-584

86 Martine de Koning, Biodiversity Prospecting and the Equitable Remuneration of Ethno-biological Knowledge: Reconciling Industry and Indigenous Interest, Intellectual Property Journal, 1997; 12 I.P.J. 261

87 Columbia University (School of International and Public Affairs): Access to Genetic Resources: An Evaluation of the Development and Implementation of Recent Regulation and Access Agreements; Prepared for the Biodiversity Action Network by Environment Policy Studies Workshop 1999

commercial exploitation. The benefit sharing scheme has been practiced as can be seen and supported from many case studies such as by *a study of the Role of a Fijian Community in a Biodiversity Project*[88] showed the bio-prospecting project in the Fiji could help the community through the benefit sharing agreement from the collections of plant and marine organisms or by *R.V. Anuradha*[89], "Sharing with the KANIS" also gave an example of the implementation of the benefit sharing in India which recognizes the contribution of the tribal community's knowledge regarding the use of a plant in which the scientists has investigated for the commercial medicines. The agreement came out to be that the inventor will share fifty percent of any commercial returns that they get from the drug with the Kanis community or by *Katy Moran*[90]; "Mechanisms for Benefit Sharing: Nigerian Case Study for the Convention on Biological Diversity" gave an example of a pilot project which focuses on the development and implementation of a process to return a benefits to the countries and culture groups who contribute to the commercialization of therapeutic for human health.

88 William G. Aalversberg, Isoa Korovulavula, John E. Parks and Diane Russell; The Role of A Fijian Community in a Bio-prospecting Project

89 R.V. Anuradha, Sharing with the KANIS: A case study from Kerala, India

90 Katy Moran; Mechanisms for Benefit Sharing: Nigerian Case Study for the Convention on Biological Diversity

Chapter 3: The Intellectual Property Rights and Patent law

The purpose of this chapter is to identify and explain the general principles of current intellectual property rights, in particular patent law. These general principles can be found in most detail in two jurisdictions, the European Union and the US. It will explain what patent law is, and how inventors of products and processes can receive monopoly protection. The essential principles are the criteria of patentability, how those criteria have been interpreted, and what inventors can receive when they have been granted patent protection. With regards to the problem of bio-prospecting, this chapter will also explain how the inventor can apply for patent protection for biological resources. Finally, the implication of bio-prospecting will be illustrated by examples which show that patent law has not been written to protect the sovereignty of States over biological resources.

3.1 Intellectual Property Scheme

It has been almost 800 years since the intellectual property scheme has been introduced even though the word "Intellectual Property Rights" has only been used for 150 years to refer to general area of law that encompass copyright, patent, design and trademark as well as related rights[91]. For example, the Romans used marks on pottery to denote its maker and a Venetian law of 1474 established 10 years privileges to those inventing new machines[92]. For the patent law, the earliest record of a grant of patent dated from 1331, to a Flemish weaver who wanted to practice his trade in England.

The IPRs have been described as a necessary tool which provides a stable and predictable environment for both right-holders and users[93]. The philosophical approach of intellectual property protection was visibly fallen into two general categories[94]. The first categories call upon ethical and moral arguments to justify intellectual property rights. This view has later on been put in the Universal

91 L. Bently and B. Sherman, Intellectual Property Law,, (1st edition 2001) p. 1

92 Cathrine Colston, Principles of Intellectual property law, (1991) p.1

93 Paul Vandoren, The Implementation of the TRIPs Agreement, (The Journal of World Intellectual Property; Vol.2 No.1 January 1999)

94 L. Bently and B. Sherman, n 91, p. 4

Declaration of Human Rights under Article 27, "Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author." For the second categories call upon instrumental justifications that focus on the fact that intellectual property induces or encourages desirable activities. The second categories recognize that the product and process they create enrich a society's culture and knowledge and thus increase the social welfare[95]. The most well-known written document of this approach can be found in the United States Constitution "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries"[96].

Intellectual property law provides certain protection of the use, exploitation, creation of an intangible works those derived from the human brain such as inventions, information, designs, trade secrets, and books. There are different forms of protection of rights in different areas of intellectual property law such as copyright[97], patents, registered designed, trademarks[98], rights in performances[99], and the law of the breach of confidence[100]. In these forms of protection, there are similarities and differences in the common grounds between these rights. Some of

95 For an overview, see E. Hettinger, "Justifying Intellectual Property Rights" (1989) 18 Philosophy & Public Affairs 31; F. Machlup and E. Penrose, "The Patnet Controversy in the Ninteenth Century" (1950) Journal of Economic History 1, 10 ff

96 United State Constitution, Article 1 Session 8

97 The copyright is a property right which provides a protection over works. These works do include literary works, artistic works, musical works, sound recordings, films and broadcasts. The first owner of the copyright usually is the author of the work. The copyright owner has rights over his work until 50-70 years depends upon the type of work. However, this right over the work is transferable or licensed. The copyright does provide the owner the rights to copy, broadcasting, giving the public performance. However, there are several exceptions that the copyright does not protection which include a copy for the purposes of a research, private study, criticism, or review. It is important to note that copyright does not only provide the economic right for the copyright owner but also provide a moral right. This moral right give the author right who might no longer be the owner the rights to control over how the work is exploited.

98 Trade mark began in 1879 in order to recognize the business image, goodwill and reputation. Trade mark has no definite periods however; it can be revoked if it has not been used within 5 years after the registration. The main objective of trademark is to make people to be able to distinguish goods or services of one product from the others.

99 The main purpose of the rights in performances is to provide a legal protection for the performers from their performance. There are two different rights which are the performer's right and a recording right. The performer's right has the right to making copy, the issue of copies, rental or lending of the record of his performance. This right in performance will last 50 years from the end of the calendar year of the performance take place. For a recording right, the performer has an equitable remuneration from the owner of copyright in the sound recording.

100 This law does provide a legal protection over information by preventing it to be used by any person. The purpose of this law is to prevent anyone from wrongful act of such information beyond the purpose for which it was disclosed to him. There are different types of information that are protected under this law starting from trade secrets to personnel details to government information.

them may prevent the unfair use such as rights in performance, copyrights while the others give the monopoly rights over the product or process, for example, patent. In order to receive legal protection, some of the defined categories must complete the registration process whereas the others might automatically receive the legal protection.

Because of its importance in terms of economic benefit arising out of the intellectual property protection, in recent years, the intellectual property scheme has increasingly been important, popular, and promoted especially by the developed countries where they have got a lead in technology. It can be seen, that after 1970s, most IPRs have been granted to every industry for the promotion of industrial products or process and research and development and has been strongly and successfully introduced in the developing nations both bilaterally and multilaterally. For instance, the United States has been discussing this issue longer than many countries and also providing her leadership in many forums internationally of how to protect the rights of inventor.

With regards to the problem of bio-prospecting, patent has been used to obtain the monopoly rights for the product and process derived of the biological resources. The patent law has permitted the use of biological resources as a substance for the production of the product and process. Therefore, this thesis will explain in details about patent law and its interpretation with regards to the problem of bio-prospecting.

3.2. What is Patent Law?

3.2.1 Patent law

Patent law is one of several laws under the intellectual property scheme. Patent law has always been regarded as a compromise between the private interests of the inventor and the public interest[101]. The private interest would be a reward of monopoly rights granted by the state over the period of time whereas the public interest would be an obligation of sufficient disclosure of the invention in such a way

101 Richard Gerster: Patents and Development: A Non-Governmental Organization View Prior to Revision of the TRIPs agreement; (The Journal of World Intellectual Property Vol.1 No.4 July 1998) p. 606

that can be carried out by those skilled in the art[102]. In order to receive a patent protection, there are criteria of patentability in which the law is allowed and the scopes of protection and exceptions to patentability are designed. It should be noted that at the beginning of the 20th century, the fields of technology where the patent law protected are limited to particular industries, but nowadays the law extends the protection to all fields of technology including biotechnology which uses the biological resources as a raw material[103]. In addition, the patent law has been extended to the international level both bilaterally through the free trade agreement and multilaterally such as the Berne convention, the European Patent Convention, the Agreement on Intellectual Property Protection[104], biotechnological directive[105], [106]

In order to be granted of patent protection, unlike copyright that is automatically given on the creation of the work, patent law demands a number of requirements to be fulfilled by the inventor through the registration process. For

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102 The motivation for privatization through patents came from the belief that innovators would be more likely to invest in developing new technologies, they knew that they would then have the temporary right to exclusive use and economic gains from the invention and be able to recoup their research investments: Lee Ann Jackson, Agricultural Biotechnology and the Privatization of Genetic Information: Implications for Innovation and Equity: (The Journal of World Intellectual Property Vol. 3 No. 6 November 2000) p. 831

103 The article 27 of the TRIPs agreement requires member to make available patents for any inventions achieved "in all fields of technology". Even though the TRIPs agreement does not define the term of technology but it can generally be defined as "the branch of knowledge that deals with the creation and use of technical means and their interrelation with life, society, and the environment, drawing upon such subjects as industrial arts, engineering, applied science, and pure science.": Random House, 1987: The Random House Dictionary of the English Language, 6th edition p. 1950

104 The member of the WTO can choose either patent or effective sui generis system or by any combination for the plant varieties protection. The reason of TRIPs to be a very important international agreement for the intellectual property protection is because it provides a very effective enforcement mechanism.

105 In 1998, the European Parliament and the Council of the European Union has adopted the directive called "the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions" with regards to biotechnology invention in order to give a clearer direction for the member of the EU to follow on biotechnology invention_. Biotechnological invention has been defined as inventions concerning products consisting of or containing biological material or processes by means of which biological material is produced, processed or used. Under article 53(b), the provision was written to clarify that the patentability of the biological subject matter including sequence or partial sequence of a gene isolated from human body or living matters by a technical process is permitted for a patent protection. As the preamble of the directive stated that "the concern of the European Parliament and the council in regards to the role and the importance of biotechnology and genetic engineering in certain industries, therefore, the Parliament wanted to ensure that the research and development in the biotechnology and genetic engineering fields will be maintained and encouraged from the inventor by providing an adequate and up to date legal protection in particular patent law_.

106 With regards to the differences in the legislation and administrative laws and practices of the member states, the Biotechnology directive has ensured the harmonization of legal practices among the member of the European Union through the clarification of points in which will give a clearer guidance to the judges and patent offices in the EU of how to interpret the law with regards to biotechnology through the recitals and articles of the directives.

example, in the UK, nowadays, there are two ways to receive the patent protection, first, through the UK patents office and second, through, the European Patent office. At the European Patent Office (EPO), the applicant must designate where they want their invention to be protected. It should be noted that while there are differences between the EPO and UK system, the patent that has been issued by the EPO will be treated as if it had been granted by the UK patent office (the designate country)[107]. The EPO has an office in Munich established by the European Patent Convention (EPC) which has come into effect on 1 June 1978 as a single applicant search procedure and a grant of member national patents in each of the countries designated. It should also be noted that after the EPC came into operation in 1973, the rules and validity and the tribunal's decisions at the EPO has so far substantially influenced the national courts. In the UK, the UK parliament had passed 1977 Patents Act which based upon EPC[108] and has substantively changed the interpretation of British patent law. Furthermore, the patent duration, the EC has introduced so called "supplementary protection certificates" which extend patent protection when there has not been possible for the applicant to fully receive their protection due to, such as, regulatory approval prior to marketing or in the area of biotechnology inventions. For biological inventions, the EC has adopted the Directive 98/44/EC of the European Parliament and of the Council[109] in 1998 to deal with patentability and scope of protection on biological inventions, an overlap between patent and plant variety protection and etc in which EU member must modify their law in accordance with the Directives.

3.2.2 Types of patent

This section will be divided into two parts. The first part will explain the patent law in Europe under the European Patent Office standards (EPO) with references to UK law when relevant. In the second part, it will explain how the patent law has been written under United States Patent and Trademark Office (USPTO).

107 PA ss. 77-8, PA r.80; EPC Art. 64.

108 European Patent Convention (EPC) has also outlined basic requirements for patent which is similar to the TRIPS (invention, industrial application, new and inventive step).

109 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998on the legal protection of biotechnological inventions

3.2.2.1 European standard

Under the EPO, there are two types of patents. The first one is called a "product patent" and the second one is called a "process patent". The product patent is protected over the physical entities or things over the periods of time. For example, a new plate warmer that can stay warm for 20 hours without using any electricity device can be protected under the patent law over the uses of a new product. For the process patent, it is protected on the activities or the action such as method or process of making such products. The process patent will protect a particular method of making a plate warmer. In addition, there is another unpopular kind of patent called "product by process patent" which means the product can be protected by a particular process claimed. A patent will be granted over a process, the protection includes both the process in question and the products that flow from that process[110]. This "product by process patent" [111]is quite useful for products, which are difficult to define as new product by any reference[112] as can be seen in many biotechnological inventions and chemical inventions, where the product by process claim may offer the only way "to define certain or macromolecular materials of unidentified or complex composition which have yet to be defined structurally"[113].

3.2.2.1.1 How to receive a grant of patent protection?

As mentioned, in order to receive a patent protection over the product or process, the inventor is required to apply for a patent over the product. In this section, it will show that there are substantial details that the applicant needs to complete in the application. In the patent application, there are four parts that the applicant needs to be completed. The first one is called the abstract. The abstract is a brief summary of the invention which indicate the title, the summary of the specification, the technical field to which it's belong, the problem and the solution that the invention attempt to solve and etc. The second part is the description. This part explains the

110 UK 1977 Patents: Act Section 60(1)© or the EPC: Art 64 (2)

111 EPC : Art 64 (2)

112 IFF/ Claim categories, T150/82 (1984) OJEPO 309

113 L. Bently and B. Sherman, n 91 p. 359

description of the scientific and technical information such as the problem that they want to find and solution that they want to achieve, what has been created, and the different between the previous product/ process, and the product is carried out. The descriptive of the invention imposed by law requirement must be descriptive enough in a way that a person skilled in the art is able to perform such product. However, if the description cannot be descriptive such as a micro-organism, the law requires the inventor to deposit of a sample[114]. The third part is the "the claim" The claim is an explanation of a primary feature of the claims as required by rule and procedure that regulate the form and must also be clear and concise enough for the person skilled in the art to understand it. The definition of claim has been stated clearly in the article 84 of the EPC that "The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description." This has been strengthen by the Enlarged Board of Appeal on case number 0002 / 98 stated that "European patent application in accordance with Article 88 EPC is to be acknowledged only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole". In addition, the claim usually define the invention by reference to the structure or element but the functional claim will define the invention by reference to the function or its perform. This functional claim has been an importance reference especially for the biotechnological invention. The last one is drawing. The drawing is a regulation of the invention which also used to interpret the claims.

In order to be eligible to receive a patent protection, the inventor must be the first person to file the application. In the EPC and the UK patent law, registration still consider "first to file" system as a tool to assess the priority date of novelty and inventiveness of a patent application. The filing date is also an important date because if the product can be patented, then the filing date will be counted as the first day of the monopoly period. However, the patentee cannot sue for infringement after the filing date, but rather after the date of publication. The date of publication is the date that the office discloses the invention to the public for the public inspection and for any opposition to such invention.

114 Recognized depositary institutions include all international depositaries under the 1977 Treaty on the International Recognition of the Deposit of Micro-organisms (the Budapest Treaty) (Modified 1980)

3.2.2.1.2 The criteria of patentability

According to the EPC and the 1977 UK Patent Act, in order the product or process to be patentable, there are criteria of patentability to be met as follows;

1. The invention must be capable of "industrial application: section 1(1) C of 1977 Act or article 52(1) of EPC
2. The product must be comprised of novelty and inventive step: article 54 and 56 of the EPC respectively.
3. The invention must not be in the exclusive lists of things that are not regards as inventions (and thus non-patentable) as stated in section 1(2)/ or article 52 (2)(3) of the EPC

3.2.2.1.2.1 Industrial Application

An invention may be capable of "industrial application" if it can be made or used industrially or in any industrial process including agriculture[115]. However, if the product cannot be shown to have a "useful purpose" as may occur in biological research which cannot indicate the function or role of the gene, it will not be patentable[116]. This point is quite important for the problem of bio-prospecting because in many cases for biological research, scientists can locate and identify a new gene structure but they may not be able to find the usefulness and purpose of this gene and vice versa[117]. Nonetheless, the meaning of whether it is industrially applicable remains for the tribunal to decide. However, to decide whether it is an industrially applicable, the tribunal might also look at what kind of person would use that invention. If the person is, for instance, a doctor or a veterinarian, rather than an engineer or an industrialist then the invention would likely fall under the exclusion but as far as the law has been interpreted, it seems to be that the usefulness of the

115 European Patent Convention, Art 57

116 Biotechnology Directive., Recital 23

117 Biotechnology Directive., Recital 24 See Chiron v. Murex (1996) FSR 153, 177 (claim to polypeptides invalid because the claim covered "an almost infinite number of polypeptides which are useless for nay known purpose)

invention is more important than who would practise that method[118]. For example, as stated in the article 52(4) of the EPC, surgery[119], therapy[120] and diagnosis will not be eligible for the patent because the court gave her interpretation of surgical and therapy in such a way which sees that the method shall not be given a monopoly because of the moral issue[121].

3.2.2.1.2.2 Novelty

The next requirement of patentability is novelty. In order to be patentable, the invention must be new and must not be part of the state of the art before the priority date of invention as defined in the Patents Act 1977 s 2 (1) or Article 54 of the EPC. Under Section 2 (2) of the UK Patent Act 1977 describes "the state of the art" means all the matter that is available in the public of the world in any forms of description such as written descriptions in journal or articles, exhibitions, sales, oral communication both by the appearance or its function before the priority date. The priority date of the invention means the date of filing the application.

The main reason novelty has become one of the criteria of patentability is that the law wants to ensure that the public will not pay the price for any invention that has already been available to them. Therefore, the next question would be how much the invention must be shown in order to constitute "to the public". The law has solved this question by saying that in order to constitute "made available to the public"; it must be an enabling disclosure. Enabling disclosure means an amount of information that discloses to the public in such a way that skilled person can put into effect[122].

It should be mentioned that there have been changes of legal interpretation of patent law in Europe about the novelty. It used to be that the law did not recognize the new purpose of a patented product because it considered such product for a

118 Cf. Cygnus/Device and method for sampling substances, T 964/99 (2002) OJEPO4 ,17. The invention was excluded under EPC Article 54(4)

119 The surgical means that any methods that operate on the living body both invasive and non invasive methods that give priority to maintain life or health of the living body.

120 Therapy means any treatment that prevent an ill effect and curative treatment that curing diseases.

121 Bruker/ Non-invasive measurement, T385/86(1988) EPOR 357, paras. 3.2-3.4

122 L. Bently and B. Sherman, 2004 p. 452

particular use[123]. The law used to interpret that the new discovering of an old thing in an old way would lack of being novel since the law did not recognize the novelty of the purpose, however, the EPC has led the way to accept the effect of an invention to be considered as an important criteria of patentability. Nowadays, such interpretation has changed to if the inventor can find a new purpose of a patented product, thus, such product can be patentable for such purpose as we can find in many pharmaceutical and biological inventions. In the other words, the patent law has extended the protection to the discovery of new benefit from the old substance if such patented product can be found a new purpose or "the new use of a known product". The change of legal interpretation had started at first for the medical uses because most of the new discovery of new purpose usually comes from the discovery of new benefit from the old substance/ product particularly in the pharmaceutical industry. For instance, in the *Eisai/ Second Medical Indication*, when the board decided that if the substance which already existed will not lack of novelty if it can prove and claim for a new purpose of such substance because the court would not only look at the discovery of a new purpose but also look at the effect of the new discovery of such invention. If such discovery will give the monopoly of sale or manufacture of the product, then the patent protection will be allowable but if such discovery will give the monopoly right over how to use such method/ discovery, thus the new discovery is not patentable. This point is particularly important in the pharmaceutical industry where they tend to claim for both the product and method of new discovery of the substance as can be seen in the interpretation of the court as follows:

> "If a functional technical feature reflected a newly discovered technical effect] has not been previously made available to the public by any of the means as set out in Article 54(2) EPC, then the claimed invention is novel, even though such technical effect may have inherently taken place in the court of carrying out what has previously been made available to the public"[124]

In addition, the law nowadays permits the patent protection over the new discovery of a new use of the old substance conducted in the old way if such invention can show a new technical effect/ purpose of such discovery as can be seen as follows:

123 See Adhesive Dry Mounting v. Trapp (1910) 27 RPC 341; R. Jacob, "Novelty of Use Claims" (1996) 27 IIC 170.173

124 G2, 6/88 MOBIL OIL/ BAYER/ Friction reducing additive O.J. EPO 1990, 93, 114; [1990] E..P.O.R. 73, p. 257

> "It is a basic consideration in G2/88 that the recognition or discovery of a previously unknown property of a compound, such property providing a new technical effect[125], can involve a valuable and inventive contribution to the art…This is apparently the reason why the Enlarged Board accepted that the use related to such a property may be regarded as a technical feature appropriate for establishing novelty[126]"

With regards to bio-prospecting problem, the above point is very important because it seems to be that a country where they have got a lead of technology and money for R&D will have more chance to find a new purpose of an old substance. However if the problem of sovereignty of states over biological resources has not been legally settled, then the developing countries who lack technological knowledge will face more problems of ownership of the product given a patent protection and loss a lot of benefits from being an owner of biological resources. In addition, the exclusive rights of patent law which can prohibit the people to use the product can have a lot of impacts to the people in many countries such as two third of India's population are the rural people who derive their livelihood from natural resources and traditional system of production and two-thirds of India's health care needs are met by traditional system of medicine whose practitioners use over 7,500 varieties of medicinal plants in their healing work[127].

3.2.2.1.2.3 Inventive Step

The other requirement of patentability is an inventive step. In order the invention to be patentable, the inventor must show that it is inventive (non-obvious).

Lord Hoffmann defined the definition of an inventive step in *Biogen Inc v Medeva Plc* as the follows:

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125 A new technical effect within the meaning of G2, 6/88 normally required the realization of a new technical mechanism which solves a technical problem. By way of contrast, an increase in activity resulting from a known technical effect, or further information or explanation concerning a known technical effect, does not constitute a new technical effect from which novelty can be derived. G2, 6/88 MOBILOIL/ BAYER/Friction reducing additive O.J. EPO 1990, 93,114; [1990] E.P.O.R. 73,257

126 T254/93 ORTHO/Prevention of skin atrophy O.J. EPO 1998, 285; [1999] E..P.O.R. 1

127 Vandana Shiva; TRIPs, Human Rights and the Public Domain; (The Journal of World Intellectual Property . Vol.7 No.5 September 2004) p. 667)

> Sometimes, it is the idea of using established techniques to do something which no one had previously thought of doing. In that case, the inventive step will be doing the new thing. Sometimes, it is finding a way of doing something which people had wanted to do but could not think how. The inventive idea would be the way of achieving the goal. In yet other cases, many people may have a general idea of how they might achieve a goal but not know how to solve a particular problem which stands in their way. If someone devises a way of solving the problem, his inventive step will be that solution but not the goal itself or the general method of achieving it.

One of the reasons why patent law requires the product to be inventive is because, according to the Court of Appeal in *PLG Research v. Ardon International*[128], "the philosophy behind the doctrine of obviousness is that the public should not be prevented from doing anything which was merely an obvious extension or workshop variation of what was already known at the priority date".

3.2.2.1.2.4 Invention

Under the Article 52 of the EPC and the Patents Act 1997, there are lists of exclusion which are not regards as an invention and thus non patentable; for example; a) discovering, scientific theory, a mathematical method, b) literary, dramatic, musical, or artistic work or any other aesthetic creation, c) scheme, rule or method for performing a mental act, playing a game or doing business or a program for computer, d) the presentation of information.

However, in recent years, the development of technology has become so advanced, as a consequence, the national courts and the EPO has come into conclusion that instead of looking at the elements of the invention, the court tends to focus on the contribution and the effect of the invention has upon. In addition, the exception could also be made if the invention which sometime falls into the list of non invention, as technical enough which contribute to the know art. In addition, in order the invention to be patentable, such invention must be physical tangible, concrete casual, and non-abstract, however, if such abstract such as a method can be put in use in a technical process and that process is carried out in a physical entity which show a technical change, thus it is patentable. Nonetheless, the definition of "technical" is

128 PLG Research V Ardon International [1995] RPC

largely left to the court to decide. In addition, in Europe, the EPO prohibits the patenting of any variety of animal or plant or any essentially biological process but not a micro-biological process or the product of such a process (this will be discussed further in 3.2.2.1.3).

In the United States, with regards to the problem of bio-prospecting, it used to be that the biological product/ process cannot be patentable as an invention. It can be explained from in the US case of *Funk Bros. Seed CO.* ***vs.*** *Kalo Inoculant Co*[129]. that anything that are or part of natural substance will not be patentable because at that time, the law still recognized the rights of the people free use as can be seen as follows:

> "The Supreme Court was faced with the question whether a mixture of naturally occurring bacteria was patentable. The Court answered the question by first stating the basic principle that patent cannot be issued for the discovery of the phenomena of nature, since they are manifestations of laws of nature, free to all men, and reserved exclusively to none. The court went on to emphasize that if the product/ process want to be an invention, then, such discovery must come from the application of the law of nature to a new and useful end[130]."

However, in the 1990s, the US Supreme Court became a leader in promoting patent protection by interpreting the law in a way which changed the interpretation of patent law with regards to the biological resources. In *Diamond v. Chakrabarty*[131], the Supreme Court allowed the genetic engineered organism as an invention, a genetically engineered bacterium capable of degrading crude oil by putting into a single organism cDNA's that coded for four different enzymes, each of which could degrade different types of oil. The Court considered that by putting all those enzymes in one single organism, has created "a non-naturally occurring manufacture or composition of matter- a product of human ingenuity "having a distinctive name, character (and) use. One of the most important say that indicated the new interpretation of patent law that "patentable subject matter to include anything under the sun that is made by man, the eligibility of patent was set not between living and inanimate things but between products of nature, whether living or not, and human-

129 Funk Bros. Seed CO. Vs. Kalo Inoculant Co, 333 US. 127, 76 USPO 280 (1948)

130 Li Westerlund, Biotech Patents: Equivalence and Exclusions under European and U.S. Patent law (2002) p. 28

131 Diamond v. Chakrabarty, 447 U.S. 303 (1980)

made inventions". This interpretation has extended the invention of the gene sequences and interactions in a product or process. The reasoning behind it would be that the court will no longer look at whether the product is made from the natural occurring or not but it tends to look whether such product or process creates anything new and its implication of it. So it can be understood that the interpretation of the court tends to favour the invention of the product and process as long as such product/ process contribute the knowledge to the society.

3.2.2.1.3 Lists of exceptions to patentability with regards to the problem of bio-prospecting

Article 53(b) or paragraph 3(f) of Schedule A2 of the Patents Act of 1977 provides that European patents shall not be granted in "any plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof". It should be noted that the EPC and the UK Patent Act of 1977 has no reason to confine on patenting the biological material or biotechnological inventions. This has been affirmed by the Biotechnology Directive 98/44/EC which specifies in the article 3 or PA Sched.A2 Paras.1(a) that an invention shall not be considerably bar from patent protection on the ground that the product or process consisting of or containing biological materials. The following paragraphs will explain the meaning of the article 53(b) or paragraph 3(f) of Schedule A2 of the Patents Act of 1977 as follows:

3.2.2.1.3.1 Essentially biological processes for the production of plants and animals

The definition of essential biological means the consistency of entirely of natural phenomenon such as crossing or selection. Therefore, to be able to decide whether an "essentially biological process" has been used, the examiner must consider how much the intervention by human made in the process and its impact on the result achieved[132]. If there is a substantial amount of human intervention, thus, it may be

132 T320/87 LUBRIZOL/Hybrid plant O.J. EPO 1990, 771; {1990} E.P.O.R. 173

patentable. There are three aspects of exceptions of patentability for essentially biological process as confirmed in the biotechnology directive as follows; the first one of exception is only apply to a process but not product claim or product by process claim. The second exception would fall if the process is a production of animal or plants; however, if such process results in the death or destruction of animals or plants, it is patentable[133]. The third exclusion is applied only on "essential biological[134]".

3.2.2.1.3.2 Microbiological processes and the products thereof

In addition, under article 53(B) of the EPC excludes a microbiological process or other technical process for that product. Microbiological process refers to a process in which micro-organisms[135] or their parts are used to make or to modify products or for specific uses[136].

3.2.2.1.3.3 Plant or Animal varieties

Under Article 4(2) of the biotechnology directive has given exception to the structure of the element that is identical to a natural element, then, such invention that request for patent must not be confined to a particular type of animal or plant varieties in order to be patentable. Similar provisions have been introduced in the 1977 Act and the EPC[137].

133 Cf. NRDC's [1961] RPC 134; Swift's applications [1962] RPC 37

134 Biotech Directive/ Art 2(2) defines it as "A procedure for the breeding of plants or animals shall be defined as essentially biological if it is based on crossing and selection" or Rule 23b of the EPC states that "A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection"

135 Micro-organisms includes not only bacteria and yeasts but also plasmids, viruses, fungi, algae, protozoa and human, animal, and plant cells, i.e. all generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory.

136 Plant Genetic Systems/ Glutamine synthesise inhibitors (1995) OJEPO 545

137 PA Sched. A2 para. 4; EPC Rule 23c(b), Implementing Regulations to the EPC

The EPO has defined the definition of plant varieties as follows:

> "The skilled person understands the term "plant varieties" to mean a multiplicity of plants which are largely the same in their characteristics and remain the same within specific tolerances after every propagation or every propagation cycle. This definition is reflected in the UPOV Convention, which is intended to give the breeder of a new plant variety a protective right (article 1) extending both to the reproductive or vegetative propagating material and also to the whole plant (Article 5(1). Plant varieties in this sense are all cultivated varieties, clones, lines, strains, and hybrids which can be grown in such a way that they are clearly distinguishable from other varieties, sufficiently homogenous and stable in their essential characteristics……"[138]

With regards to the problem of bio-prospecting, it can be seen that patenting a plant variety is not possible in Europe because if anyone would like to be grant a property rights in any new plant variety, then the Plant Variety Protection[139] of the UPOV under the International Convention for the Protection of New Varieties of Plants[140] would be the place for it. However, the article 4(2) of the Biotechnology Directive has opened up that if a claim encompasses more than one variety it is potentially patentable.

For the animal varieties, in the article 53(b) of the EPC has also excluded animal varieties from patentability. For the reason of why it was excluded could be seen that "the most obvious reason for this must have been the intention or at least the keeping open of the possibility to create such law for the protection of animal varieties later on"[141] However, the law has opened up the possibility of patenting the animal as long as it does not confine with a particular animal variety[142].

138 T49/83 CIBA-GEIGY/ Propagating material O.J. EPO 1984, 112; [1979-85] E.P.O.R. 758

139 To be explained in details in chapter 4

140 For UPOV, in 1961, the International Convention for the protection of New Varieties of Plants under auspices of the UPOV was signed in Paris and entered into force in 1968 and later on revised in 1978, and 1991. It should be noted here that the international communities have also given the alterations for the inventor to choose the system in which plant varieties can be protected. In the recent decades, the developments of new varieties have been taken on a larger scale and have become a major industrial activity_. The UPOV model is one of the models that have been used for the plant varieties protection since 1970s. However, the UPOV models have been changed, amended, and adopted through the UPOV 68, 78, and 91.

141 Harvard/ Onco-Mouse (2003) OJEPO 473, 499

142 Biotechnology Directive/ Art 4(2)

3.2.2.1.4 Ownership

With regards to the ownership or the entitlement, the EPC leaves it to the national court to interpret the law in this matter. Under the UK Patents Act 1977 refers the owner as the proprietor of a patent who is able to exploit and control the use that is made of a patent. They are also able to make decisions about when and the conditions under which a patent can be assigned, licensed, mortgaged. The owner of the patent is also the person who is able to sue for infringement after the date of publication. It is important to identify who is actually the inventor or the joint inventor/s of the invention. It can either be identify as the applicant of the invention or when an individual/s want to claim as inventor/ joint inventor who contribute such invention for any benefit arising out of such invention. It would not be an issue if it falls under the first category. However, if it falls into the second category, then, it is important to look at who should be claimed as a main contributor of the invention. In order to do that, the court can both ask the application/ the claimant to identify their contribution for the development in the elements of the invention or identify the essential part of the invention first and then determine who play a significant part of such invention. Before doing so, it is important to find the interpretation of the inventive contribution because the definition may be varied in different areas of technology. However, the ownership might be identifiable when we used the problem-solution approach because the court can look at who pose the question and who provide such technical answer. However, if we go into different areas, as mentioned, problem-solution approach may not be appropriate to use. Nonetheless, the universal recognition of being an inventor or a joint inventor would be a person who provides their help/ idea which can solve the problem or find something that has never been technically found before.

With regards to the inventive contribution, there has also been a new name called “non-inventive contribution”, which usually regards them as material or money or facilities or labour. According to Moore v. Regents of the University of California[143], the court has recognized that a crucial starting material will not be regarded as an inventive contribution if such material can be generally or publicly

143 Moore v. Regents of the University of California, West California Reports 1998, July 21; 249: p 494-540

found from anywhere. However, it might seem to be different to the EC Biotechnology Directive 98/44/EC under the preamble 26 which states that,

> "whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law".

The above paragraph is very important to understand because the above law recognizes the rights over person body or non-inventive contribution shall result to the prior informed consent and thus can lead to the compensation for the benefit arising out of such material. Therefore, if this thesis would like to apply the above law to the bio-prospecting issue then biological resources, which are already in the public domain, would require a prior informed consent and thus the benefit sharing which would be arising out of the utilization before it applies for patent protection as a non-inventive contribution.

3.2.2.1.5 Infringement

There are two types of infringement. The first one relates to an immediate engagement with the patented product or process called "direct infringement". The second one relates with a person who facilitates the act of infringement called "indirect infringement". However, in order to be infringed[144], there are three questions that court tends to look at. First, what types of activities that constitute an infringement? Secondly, whether activity complained falls within the scope of the patent monopoly. Thirdly, it must be determined whether the defendant is able to make use of any defences to infringements that are available to them.

For a direct infringement, it is important for the owner to show that the defendant has violated the right of the inventor. The right of the inventor has been given according to the law. Those rights can be making, disposing of, offering to, using, importing, and keeping the product. The liability in the case of direct infringement is absolute which mean that the patentee does not need to show that the

144 L. Bently and B. Sherman, n.91 , p. 487

defendant know that they were wrong[145]. The patentee has the right to make, sell, import (in terms of course of trade or for the purpose of profit) and keeps (act as custodian). For the rights to keep the product the court has not been able to define the definite definition of 'keep', but it seems to be that the court would look at the purpose of keeping the product. If anyone keeps the product as a "keeping in stock"[146] rather than "acting as a custodian for the purposes of the business in order to make use/benefit of them", it would not be called an "infringement". For the infringement of patented processes and products by such process, the patentee must show to the court that the defendant intend (it is not an absolute infringement)/know to make an unauthorized use of the process.

For an indirect infringement, it means that infringement arises when a person contribute to an infringement, but does not directly take part of such action such as supplying essential components of the products. There are three elements of indirect infringement which must be satisfied in order to be called an indirect infringement[147]. First, the proprietor of the patent must establish that the supplier by the defendant is an essential element of invention. Secondly, the defendant must have an interest of a benefit of infringement. This means that the imposition of knowledge requirement ensures that person who does not knowingly benefit from the misuse of a patent are not caught as indirect infringement. Thirdly, there must be a legitimate reason why a person supplies such product. However, there are several exceptions of infringement, which are private non-commercial uses, experimental uses, and research and development.

3.2.2.2 The USPTO standards

In the United States, the Patent and Trademark office (PTO) is responsible for determining patentability and issuing patents. The most recent Act was the Patent Act of 1952, codified at Title 35 of the US Code, which has been modified to conform to the laws of other countries and international agreement. In the federal system like in the US, the state has the power to create laws regarding ownership and transfer of

145 L. Bently and B. Sherman, n.90 , p. 487

146 Mc Donald v. Graham (1994) RPC 407

147 L. Bently and B. Sherman, Intellectual Property Law, 2nd edition 2004 p. 497

ownerships; however, the federal government creates laws regarding the standards of validities of patent and the grant of patent rights. When there is a jurisprudent, the federal courts interpret the law and are the proper forum for filing the infringement actions. The federal court pre-empts[148] state law regarding patent validity and infringement. When there is an infringement in the US, the litigants can appeal federal district court patent decisions to the US Courts of Appeals for the Federal Circuit which replaced the Court of Customs and Patent Appeals and Court of Claims in 1982. However, if the litigants want to challenge the Federal Circuit court decision, then the litigant can appeal to the U.S. Supreme Court in the United States, the Congress has established the subject matter that can be protected under the US patent law. There are three types of patents in the US[149]:

1) Utility patents may be granted to anyone who invents or discovers any new and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof;

2) Design patents may be granted to anyone who invents a new, original, and ornamental design for an article of manufacture; and

3) Plant patents may be granted to anyone who invents or discovers and asexually reproduces any distinct and new variety of plant.

With regards to the bio-prospecting problem, the plant patent is worth for consideration. For the plant patent, the US patent law allows plant to be patentable since 1930. Under the US patent law, the inventor of such plant is the person who first appreciates the distinctive qualities of such plant and reproduces it asexually, therefore, a plant can be created or it can be discovered to receive a monopoly protection. In order to receive a patent protection for a discovery of plant, such plant must be discovered in a cultivated area and thereafter asexually reproduced. Asexually reproduction means that the plant is reproduced by means other than seeds such as butting, grafting and such plant must be novel and distinguishable from other varieties. If plant was found in nature, then such plant cannot be patented. However, if such plant was produced sexually, then such plant will be protected under the 1970

148 Pre-emption is the authority of federal government to preclude the states from exercising powers granted to the federal government.

149 The United State Patent and Trademark Office information available at www. uspto.gov (6 March 2006)

Plant Varieties Protection Act (PVPA) as amended in 1994 to be compatible with the UPOV 1990. Under the US PVP, it provides legal IPRs protection to inventors of new varieties of plants that are sexually reproduced (by seed) or are tuber-propagated. The PVPA is administered by the United States Department of Agriculture whereas the patent law is administrated by the USPTO. In order to be certified for a PVP of a new variety, the owner of a variety must show that the new variety is new, distinct from other varieties, and genetically uniform and stable through successive generations. The term of protection is 20 years for all crops and 25 years for trees, shrubs, and vines. The owner of a U.S. protected variety has exclusive rights to multiply and market the seed of that variety.

In addition, nowadays, the US amended the law by allowing the plant to be protected under the utility patent; however, such plant must be produced by humans and meet the requirement of utility: novelty, non-obviousness and must be issued for elements of plants such as genes, DNA, proteins, buds, pollen, plant based chemicals. Even though the utility patent is harder to acquire than plant patent but it provides a stronger form of production. For a length of patent term, it used to be a period of patent terms was 17 years but as of June 7, 1995; the length has been extended to 20 years from the date of filing.

3.2.2.2.1 Patent Requirements in the USA

There are four requirements for a patent in the US. Those are useful, novel and non-obvious and must falls into one of the classes described in the statue. For the requirement of usefulness, the law asked the inventor to prove that the invention are created or discovered for some useful purpose. The applicant must show to the USPTO that the invention must have a use or purpose and be capable of performing its intended purpose. For the requirement of novelty and prior art, the patent protection will not be given to an invention that was known and used by others printed or published in the US or in the foreign country before the date of invention or if the application for the patent is made more than one year after sale or public disclosure, use, offer of sale in the US. For the requirement of non-obviousness, the patent protection will not be given to a product that is not sufficiently different from what has been used or described to a person having ordinary skill in the area. For the

Statutory Clauses, the law requires the invention to be fall within one of the statutory classes provided in 35 U.S.C. 101 such as useful process, machine, manufacture, or composition of matter. The law give board categories as established by the Supreme Court, "anything under the sun that is made by man" provided that it meets the statutory requirement. When the applicant files for the application, the applicant is not required to indicate the statutory class as long as a patent examiner determines that the invention falls within one of the categories.

This thesis is of the opinion that the US criteria of patentability are similar to the European criteria, however the main difference between the US and the European patent is about who shall be the first person to receive a patent protection. Under the section 102(g) of the US patent Act states that an inventor is entitled to a patent unless the invention was made first by another person who has not abandoned, suppressed, or concealed it or so called "first-to-invent" principle. The US has this unique system in the international community. The reason behind this principle is that the lawmaker believe that the creator of the invention should be rewarded for his/her work, and not for technical steps such as filing patent applications, whereas in the European countries, it goes to the person who files for the protection. They are so called first-to-invent system and the first-to-file system.

3.2.2.2.2 Infringement in the USA

The rights grant by the USPTO is similar to the EPO. The owner of a patent may exclude other from making, using, selling, and etc through out the United States; however, the patent owner may license or assign his or her rights to different parties. The law also allows the patent owner to sue the purchaser of the infringed products, however, it usually is not a case when it goes against consumers of mass produced devices because it usually exercises in the case of expensive or limited inventions.

It can be summarized that criteria of patentability both in the US and Europe are very rigid and is applied to the entire product and process in any fields of technology. It can be seen that the inventor does not need to be concerned with the issue of sovereignty of state because the only thing that the inventor requires to receive a monopoly protection is to meet the criteria of patentability. Nowadays, the intellectual property law has extended its scope of protection wider than before. In

the US, the scope of protection has extended to the plants and animal varieties whereas in the Europe, the interpretation has tended to change to allow the patentability of living things as long as it does not confine to a particular variety.

3.3. The examples of the implication of the problem of bio-prospecting

In this section, three cases will be used to illustrate the problem of bio-prospecting. These three cases are the Turmeric case, the Neem Tree case, and the Basmati case. It should be noted that the causes of these three cases were different. The first two cases, the Turmeric case and the Neem tree case, occurred because of the inability of the state to monitor their traditional use of the biological product when the invented product which used the traditional knowledge had been filed for patent protection. In the order words, the patent office gave patent protection to the product even though it lacked novelty and inventive step, because there were no objections at the time of filing application. For the third case, the Basmati case happened when the Patent office gave the monopoly rights over the product and allowed it to be called a name similar to the product in the originating area. The Indian government filed a complaint with the USPTO who allowed the product to use the name of Basmati Rice which has been used in Indian for centuries. In these three cases, the Indian government was lucky enough to find out about these three problems because a lot of times, it is impossible for the patent office to be able to monitor whether what product/ process has been granted a patent protection. In addition, the process of filing a complaint to the patent office or to the court could be very time-consuming and very expensive to hire the lawyer to challenge the patent office in particular when it comes to technical issues. It can be seen from the comment in the Basmati case by Shiva and Ruth Tripathi of the NGOs called ActionAid said "However, filing cases and challenging individual patents is a costly affair. It can be very expensive to challenge patents on a case-by-case basis by pointing out that American lawyers demanded a deposit of nearly $500,000 from Pakistan - another country whose farmers grow basmati - to challenge the patents[150]."

150 Chakravarthi Raghavan, NGOs launch campaign against basmati patents, available at http://www.twnside.org.sg/title/basmati2.htm (15 September 2006)

The details of the cases can be understood as follows:

3.3.1 The Turmeric case

Turmeric is an herb grown largely in East India, and the powder product has several uses worldwide. The powder has a deep yellow colour and bitter taste and can be used as blood purifier in treating the common cold, anti-parasitic for many skin infections, ingredient in cooking, a dye, and other medicinal uses as well.

In the mid-1990, the USPTO granted a patent number 5,401,504 to two Indian-born scientist on the use of Turmeric as a wound healing agent. The invention claimed that use of turmeric at the site of an injury and/or by oral intake would promote the healing of a wound. Under heavy media coverage, the Council of Scientific and Industrial Research under the Department of Science and Technology, the Government of India filed a complaint to USPTO challenging the novelty of the patent claim that the turmeric has been used medicinally for thousands of years as a "common knowledge" in India for centuries as it can also been seen by the ancient Sanskrit writing.

As the requirements of U.S. law, it was necessary to find adequate evidence in the form of printed and published information that would establish that the manner of use of turmeric as in the claimed invention, was known before the patent was claimed and, therefore, the patent could be invalid because there is a clause in US patent laws that it will not accept any information already available in published or written form anywhere in the world as common knowledge[151].

As a result, India was able to furnish published evidence to support their case that the healing characteristics of Turmeric are not a new invention and as such cannot be patented. There were 32 references were located, some of them were more than hundreds years old and in the Sanskrit, Urdu, and Hindi. The USPTO later revoked that patent stating that the claims made in the patent were obvious and anticipated, and agreeing that the use of turmeric was an old art of healing wounds.

151 35United States Code Patent: 102

3.3.2 The Neem tree case[152]

"Azadirachta indica" is commonly known as the Neem which can be largely found in India. There are approximately 14 million neem tree in India. Access to neem products was very cheap and easy to get. The Neem has been extracted and used for centuries as a symbol of Indian indigenous knowledge. In every virtues of Neem, the tree contains numbers of potent chemicals which can be used in many fields such as medicine (leprosy, skin disorders, and constipation), toiletries (toothpaste, soap), contraceptive, timber, lamp oil, and agriculture. The neem tree has many versatile traits that can be traced back to the Upavanavinod, an ancient Sanskrit treatise dealing with agriculture. This treatise cites the neem tree as a cure for ailing soil, plants and livestock. For example, some people chew neem leaves in the morning for 24 days to protect the body from diseases like hypertension and diabetes. The juice of the neem tree (5ml) mixed with equal amounts of honey reduces oozing from ears and also removes inflammation. The ash of the dry neem leaves is used to remove urinary stones. The most important, and controversial, is its use as a potent insecticide. It is effective against approximately 200 insects. Making pesticides emulsion does not take highly sophisticated equipment, as native peoples have been making it for over 2000 years. Indians have developed their own process of cracking off the top that would then be used on plants as a pesticide. Neem based pesticides, medicines and cosmetics have been produced by some laboratories in India, but there has not been an attempt to make ownership of the formula legal because Indian law did not allow agricultural and medicinal products to be patented.

In 1971, a timber company in the United States found out that the neem tree's usefulness in acting as a pesticide and began planting neem tree seeds. Since 1985, there were over a dozen US patents have been taken out by US and Japanese firms on formulae for stable neem-based solutions, emulsion, and many more. USPTO had granted patent No 4946681 in 1990 for improving the storage stability of neem seed extracts containing azadirachtin (a naturally occurring substance that belongs to an organic molecule class called tetraortritenoids). In 1992, W.R. Grace secured its rights to the formula that used the emulsion from the Neem tree's seeds to make a

152 Information available at www.american.eud/ted (2 February 2006)

powerful pesticide and had set about to manufacturing and commercialising the product in India.

The controversy over who has the rights to the Neem tree raised many questions. India claims that what the US Companies are calling discoveries are the actual stealing and pirating of the indigenous practices and knowledge of its people because they believe that the patented product had been applied to methods of extracting the natural chemical in the form of a stable emulsion or solution, which are simply an extension of the traditional processes which had been used for ages. Another issue is whether the neem tree is patentable, since it is a product of nature, which shows that it is not a result of innovation and discovery.

However, Grace argued that Grace did not ask for a patent protection on the tree itself, but rather on the process of making the emulsion or on a synthetic form of a naturally occurring compound. A synthetic form of a naturally occurring compound may be patentable, because the synthetic form is not technically a product of nature, and the process by which the compound is synthesized may be patentable. Grace believed that this process is an invention because it entails manipulation yielding greater and better results and also different from the original product of nature and the traditional method and thus it is patentable. The US based company was trying to patent the product derived of the neem tree in Europe. The patent had been filed by USDA and W.R. Grace on December 12, 1990. On 14 September, 1994, the European Patent Office granted a patent for a particular method for controlling fungi on plants which comprised contacting the fungi with a neem oil formulation. However, the European Patent Office (EPO) received a challenge file in 1995 on the ground that the use of neem extracts for fungicide and pesticide has been practised for centuries and investigated scientifically and commercially for decades, prior to the claim made by the USDA and Grace. The Case ended by revoking the patent in which the EPO pointed out that this patent was based on the existing knowledge systems and lacked novelty and inventiveness.

3.3.3 Basmati case

For the Basmati case, it happened when the US Texas based company filed a generic patent protection on basmati rice lines and grains to the USPTO with 20 broad

claims which designed to create a complete rice monopoly patent which include planting, harvesting, collecting and give RiceTec to call its own rice both within the US and international and be able to label its rice as “Basmati” for its export. RiceTec Inc was issued the Patent number 5663484 on Basmati rice lines and grains on September 2, 1997. The invention also relates to a novel means for determining the cooking and starch properties of rice grains and its use in identifying desirable rice lines.

The Indian gave a quick response to the USPTO because the India and Pakistan will directly effect from the new patent protection because annually the India and Pakistan exported about 45,000 tonne to the US market in which it accounted for 10 percents of the total Basmati Exports, not to mention the EU, UK, Middle East, and West Asia. In addition, everybody knows that the name “Basmati” has been called for the long grain aromatic rice grown only in Punjab, Haryana, and Uttar Pradesh and especially in the foothills of Himalayas for thousands of years.

The Indian Government filed petition to the USPTO to re-examine the grant of patent in respect of particular claims which were related to grain. The Indian government provided a good evidence of prior art to get cancellation of all generic claims related to Basmati seed and rice lines. At the end of the case the Rice Tec reconsidered to cancel most of other 15 claims except the remaining 5 claims which satisfied all the criteria for patentability. The Patent Examiner has also changed the title of the patent from "Basmati Rice Lines and Grains" - covering a broad generic claim to invention of Basmati, to invention of Basmati to "Rice Lines Bas867, RT 1117, RT1121” which are restricted to the specific breeding done by RiceTec and not open-ended as the original patent was, which covered wide ranges of plant height, grain size, aromatic quality including the qualities of our traditional Basmati. The patent holder now cannot claim the unique qualities of our Basmati nor the unique name "Basmati” since the argument of the Indian pointed out that since the Basmati grain as well as the characteristics of grain is not novel and is not unique respectively, therefore, the plant, rice lines, and seed derived from the grains cannot be unique are not novel and thus the Rice Tec cannot be legitimate to claim that they have invented a unique rice seed, rice plant and rice lines.

In the conclusion, it can be seen that these three cases are the examples of the problem of bio-prospecting. There are three problems found from these three examples as can be understood as follows:

1. The first problem arises from the failure or inability of state to control the use of their biological resources and traditional knowledge. This can be seen from the examples of Turmeric case and Neem Tree case where the scientists could patent the traditional use of Neem and Turmeric in the US.

2. The second problem arises out of the legal issue. The patent office does not require the patent applicant to disclose the origin of biological resources, therefore, the principle of sovereignty of state over natural resources has not been recognized.

3. The third problem arises from the inefficiency of the patent office to check the patent application with regards to the criteria of patentability as can be seen from, for example, the Turmeric case and Neem case. In this case, the Indian government could show to the Office that the patent given to these two cases should lack of novelty.

Therefore, these three cases could be seen as the examples of the problem of bio-prospecting. Therefore, it is necessary for the patent law to be rewritten in order to deal with the problem of bio-prospecting. In the next chapter, this thesis will suggest how to change the patent law in order to deal with the problem of bio-prospecting.

3.4 Conclusion

In this chapter, it has explained how the patent law is developed and interpreted in Europe and the US in order to give a background for a reader to understand the patent law and its interpretation in two key jurisdictions. This thesis sees that the interpretation of patent law has only been interpreted in favour for the expansion of the process of technological development and the growth of the technological industry. However, there are a lot of literatures disagreeing with the intellectual property schemes[153] and have recommended to stop developing biotechnology or abandon the protection of intellectual creation on biological resources. For example, Marcelin M. Tonye wrote that the public ownership of the

153 Please see Chapter 2: Literature review

biological resources shall be determined through the change of law of self-determination in order to address the problem of bio-prospecting that the concepts of territorial rights and self-determination of rural communities have not been built into many laws which mean that addressing land ownerships/ territorial rights and self-determination appears to be a step forward that biodiversity-rich countries are expected to make themselves in the sense of giving the communities the rights over the land where these resources are exploited and the right to determine who can have access and how this should be done[154]. The other arguments can be seen by Vandana Shiva regarding the right of the people who normally live and own the biodiversity in which it contradicts the concept of IPRs which transfer the public rights to private right as can be seen that most of the third world communities meet their basic needs through biodiversity and indigenous knowledge, knowledge of breeding of nutrition and medicinal plants, therefore, biodiversity and indigenous knowledge are centred on human rights and the economic security of people[155]. From the above argument, it can be seen that what the lawmaker can do for the problem of bio-prospecting is to look at how the patent law should still be developed for the expansion of technological and guarantee of the investor's return but at the same time it also needs to recognize the sovereign of state over her biological resources under the principle of international law which has been practiced for centuries.

In the next chapter, the analysis of patent law will be expanded to incorporate TRIPs agreement and the importance of how TRIPs agreement has been written and interpreted will be explained. It should be noted that TRIPs is considered to be the most important of IPRs agreement because of its enforcement mechanism and the large number of country who are party to the agreement. The chapter will analyze whether the reinterpretation or amendment of TRIPs agreement is feasible to address the problem of bio-prospecting.

154 Marcelin M. Tonye, Sui Generis Systems for the Legal Protection of Traditional Knowledge and Biogenetic Resources in Cameroon and South Africa; the Journal of World Intellectual Property, (Vol.6 No.5 September 2003) p. 773)

155 Vandana Shiva; TRIPs, Human Rights and the Public Domain; The Journal of World Intellectual Property (Vol.7 No.5 September 2004) p. 667

Chapter 4: the legal critique of TRIPs

The linkage between the problem of bio-prospecting and TRIPs arises when Members of the WTO which abided by TRIPs' articles must allow the biological resources to apply for patent protection as a product or process as stipulated in the Article 27. The TRIPs agreement requires the member countries to establish minimum levels of intellectual property scheme or to amend laws concerning patents to conform to the TRIPs agreement. The importance of the TRIPs agreement in terms of the commitment in the text agreement, the rules of the enforcement towards the members of the WTO, and numbers of member who party to the agreement[156], the effective enforcement mechanism provided in the Article 41 of the TRIPs[157] agreement and Article 23 of the GATT 1947 which guarantee the rights of the patent holder have been seen as reasons of why TRIPs is an important and powerful international agreement for IPRs scheme. It should also be noted that one of the main reasons of why the TRIPs agreement is a powerful agreement and the members tend to strictly follow what they have been agreed can be understood from the Understanding on Rules and Procedures governing the Settlement of Disputes (DSU). The dispute settlement system provided by DSU is considered to be a central element in providing security and predictability to the multilateral trading system[158]. In the DSU, it allows the party concerned to compensate and suspense the concessions of the obligations if the other member concerned could not reasonably bring the measure found to be inconsistent with an agreement into compliance.

As mentioned that in the past few years, there have been a lot of criticisms from the developing nations about the implication of the TRIPs agreement to the WTO members especially on the questions of legitimacy and suitability of the TRIPs agreement to the developing countries[159]. Those questions include the problems of the content in the text agreement, the socio-economic and technological differences of

156 As of 23rd July 2008 1st January 2007, 153 countries has become a member of the WTO.

157 Article 41 of the TRIPs agreement stipulates on the general obligation of an enforcement of intellectual property rights under the TRIPs agreement. The article 23 of the GATT 1947 stipulates on the Nullification or Impairment.

158 Article 3.2 of the Dispute Settlement Understanding of the Marrakesh Agreement of Establishing the World Trade Organization

159 It should be noted that the TRIPs agreement is the combination between the European and American intellectual property law.

the member countries when it comes to the implementation, the implication of new technology and intellectual property protection to vital sectors in the developing nations and etc. These result to the identification of several problems which have been asked, raised, and discussed in the meetings both at the high-ranking officials and ministerial levels in order to find solutions to the problems including the problem of bio-prospecting and the patent law.

The problem of bio-prospecting and patent law is one of many problems which have been loudly complained by members of the WTO especially the South that the North can patent the product and process from bio-prospecting as long as they can meet the criteria of patentability and does not have to recognize the sovereignty rights over natural resources of the South[160]. The only thing that the TRIPs agreement guarantees is that patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application[161] in order to ensure that the intellectual of the innovator will be protected as a reward of his/her contribution, the investment of the entrepreneur will be guaranteed, and thus, it will enrich society in the long run. It can be said that the above reasons are an assumption which depends on where the patent is granted and enforced and how they calculate the costs and benefits. The problem arising out of the patent protection both at the domestic level and discussion at the international forums indicate that the IPRs in particular patents might only bring benefits to the country where their socio-economic conditions are well designed whereas it might be a cost for many countries in particular developing nations. In addition, the developed countries have strengthened the IPRs commitment through aggressive intellectual property protection scheme in the bilateral agreement (TRIPS Plus agreement) with a trade concession in which it has left no choice for the poor countries, but to take what the developed countries offer. This argument has been supported by *Elizabeth Henderson* who explained the implication of patent law under the TRIPs agreement by pointing out that the western style IPRs in particular patent law were not suitable to the developing nations because of the differences of the environment, level of technology, expertise, training, capital, infrastructure to

160 World Trade Organization, Information available at www..wto.org (4 July 2004)

161 Agreement on Trade Related Aspects of Intellectual Property Rights/ art 27.1/ (http://doconline.wto.org) (4 July 2004)

support the research based industries where the developing nations does not have in which the product and process that to receive the patent protection is needed.

This chapter will be divided into two sections. The first section will explain that in order to answer the research question of how Thailand can legally deal the problem of bio-prospecting, it is necessary to examine the importance of the TRIPs agreement and whether the text agreement in the TRIPs agreement allows the member of the WTO to implement TRIPs different than what it is. This chapter introduces two options. The first option is to implement the article of TRIPs differently through reinterpretation and the second option is to amend TRIPs. Therefore, in order to find which option should be chosen, it is necessary to examine the articles in the TRIPs agreement to see whether there is any room for the WTO member to go for the first option when it comes to bio-prospecting issue or the second option is the only choice.

For the second section of this chapter, it will show how the solution to the problem of bio-prospecting has been discussed at the international level. The second section will show that there have been communications among members of the WTO before TRIPs council[162] whether the recommended tool for the problem of bio-prospecting should be done inside or outside the scope of patent law. This section will show to the reader that the communications made at the international meeting was still in political disagreement and thus it will be politically difficult to reach consensus.

4.1 What is TRIPs agreement?

The Agreement on Trade Related Aspects of intellectual Property Rights (TRIPs) was part of the Marrakesh Agreement establishing the World Trade

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162 TRIPs agreement/ Art 68 stated that the Council for Trade-Related Aspects of Intellectual Property Rights or so called the TRIPs Council shall monitor the operation of this Agreement and, in particular, Members' compliance with their obligations hereunder, and shall afford Members the opportunity of consulting on matters relating to the trade-related aspects of intellectual property rights. It shall carry out such other responsibilities as assigned to it by the Members, and it shall, in particular, provide any assistance requested by them in the context of dispute settlement procedures. In carrying out its functions, the Council for TRIPS may consult with and seek information from any source it deems appropriate. In consultation with WIPO, the Council shall seek to establish, within one year of its first meeting, appropriate arrangements for cooperation with bodies of that Organization. It opens to all members of the WTO and is responsible for administering the TRIPs agreement.

Organization. The objective of the TRIPs agreement is an attempt to narrow the gaps of the member countries in the way these intellectual property rights are protected around the world, and to bring them under common international rules with an effective enforcement mechanism. The TRIPs agreement requires the member countries to establish minimum levels of intellectual property scheme, if necessary by changing their law such as the copyrights and related rights, patents, trademarks, geographical indications, and etc in accordance with the TRIPs agreement.

With regards to the general provisions and basic principles of the TRIPs agreement, the TRIPs agreement gives the importance to the National Treatment Principle[163] and the Most-Favoured Nation Principle[164]. TRIPs is also intended to contribute to the promotion of technology and differences of economic and social conditions[165] and the protection of public interest[166].

Patent law under TRIPs requires the member country to give the exclusive rights of monopoly to any inventor who meets the criteria of patentability except the product and process that falls into the exceptions of patentability[167]. TRIPs give the term of protection for twenty years counted from the filing date[168]. For the scope of protection, TRIPs has provided the scope of protection includes making, using, offering for sale, selling, or importing for both the product and process in the other words, the TRIPs agreement provides the monopoly right over the product or process to the patent holder[169] . It should be noted here that the scope of protection under the

163 Article 3 of TRIPs: Each member shall accord to the nationals of other members treatment no less favourable than that it accords to its own nationals with regards to the protection of intellectual property.

164 Article 4: of TRIPs: With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nations of all other Members.

165 Article 7 of the TRIPs: The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

166 Article 8 of the TRIPs: Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

167 Agreement on Trade Related Aspects of Intellectual Property Rights/ art 27.1

168 Agreement on Trade Related Aspects of Intellectual Property Rights/ art 33/ (http://doconline.wto.org) 8 November 2005

169 Agreement on Trade Related Aspects of Intellectual Property Rights/ art 28/ (http://doconline.wto.org) 8 November 2005

patent law give the monopoly rights over the product or process including the product or process derived of the biological resources.

In order to be eligible for the patent protection, the TRIPs agreement requires the product/ process to be new, involve an inventive step and are capable of industrial application[170]. The meaning of the criteria of patentability is largely left to the national office to interpret; however, the meaning has become similar throughout the members of the WTO. The interpretation of the criteria of patentability could be understood from the previous chapter.

With regards to plant and animal varieties, the TRIPs agreement states it clearly that "Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof"[171]. In the USA, the law has provided for the protection of plant varieties both by the patent and *Sui generic system* (PVP) as a dual system whereas in the European countries, the patent law goes along with the European Patent Convention (EPC). The EPC has provided a similar patentable subject matters and scope of protection with TRIPs but the EPC has specifically said that both plant and animal varieties are not patentable subject matters (under the Patent Act 1977 s 1(3) (b) and the article 53(B) of the EPC), therefore, the members of the EPC do provide the protection of new plant varieties through the *sui generic system* which go along with the International Convention for the Protection of New Varieties of Plants of The International Union for the Protection of New Varieties of Plants (UPOV)[172].

4.2 Changing TRIPs Agreement

There are two options to address the problem of bio-prospecting under the TRIPs agreement. The first option would be to keep the text of the TRIPs agreement as it is but implement the TRIPs differently through the re-interpretation of the TRIPs agreement or go for the second option which is to amend the TRIPs agreement.

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170 Agreement on Trade Related Aspects of Intellectual Property Rights/ art 27.2/ (http://doconline.wto.org) 8 November 2005

171 Agreement on Trade Related Aspects of the Intellectual Property Rights/ at 27.3 b/ (http:doconline.wto.org) 8 November 2005

172 Please see chapter 7 for a detailed explanations of UPOV

For the first option, since the South sees that the intellectual property protection under TRIPs does not provide a fair deal to the developing nations, therefore, the developing nations see that it would be better to implement TRIPS different. One way of implementing the TRIPs differently might be to reinterpret TRIPS in the context that allows the developing nations to implement TRIPs differently than it used to be. This new approach might give the way for the developing nations to re-balance the power of TRIPs through mechanisms in order to ensure the right of the innovator and the rights of the developing countries is fair.

In order to reinterpret the TRIPs agreement, this thesis must examine the TRIPs agreement whether the texts of this agreement provide any room for the developing nations to reinterpret TRIPs in which recognize the rights of the developing nations to develop their economies as seem appropriate and truly reflect the socio-economic conditions of the member countries and to be able to bring any necessary measures to assess the appropriateness and suitability of the intellectual property protection to the product and process.

Therefore, in order to reinterpret, understand, or to bring any necessary mechanisms for the bio-prospecting problem to counter the TRIPs agreement, it is necessary to examine whether TRIPs' articles allows the member to do so.

4.2.1: Can the member of the WTO implement the TRIPs agreement differently through the reinterpretation?

This thesis would like to suggest that there would be three articles in the TRIPs agreement those could be used to reinterpret the article 27.1. Those articles are article 7, 8 and 27.2.

4.2.1.1 Article 7 which is entitled "objectives".

> Article 7: "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligation.

In this article, it firstly recognizes the importance of technological promotion and innovation; however, it also recognizes that the protection and enforcement of

intellectual property rights should come with the mutual advantage of producers and users of such technology. In addition to that, the article points out that such protection and enforcement should assist the member's socio-economic welfare.

According to the criticisms of the TRIPs agreement with regards to the problem of bio-prospecting over the past few years, the South sees that the agreement has not really showed the significant advantage to the users of the technology and assisted to social and economic welfare in particular to the developing nations. Therefore, in order to use this article to support the argument of reinterpretation for the bio-prospecting problem, the member countries must prove that the TRIPs agreement does not give any advantage to the users of the technology and does not assist to the member's social and economic welfare of the South as much as it costs to them. It should be noted that the statistical data to be proven by the South might be difficult to show to and in conflict with the North and the conflict might cause the legal dispute at the panel. The reasons would be, first, the benefit and cost of IPRs between the North and the South is definitely different because the North strongly believe that the Patent will benefit the society in the long run whereas the South sees that they will pay more price for the monopoly protection from the technology they receive from the North, at least in the short term and there is no guarantee that they will pay less in the future since the technology keeps developing. As a consequence, if the member of TRIPs would like to use this article to implement TRIPs differently, then there will be a lot of conflict in the data between the North and South and the South might not be benefit from the new product/ process because the North would not like to export to these countries. Nonetheless, this article at least shows that the member can implement TRIPs difference than it used to be if the South can provide a good rationale and solid data to support for the reinterpretation.

4.2.1.2 Article 8 which is entitled "principles"

> Article 8: principles; 1.Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

In this article, the TRIPs agreement allows its member to formulate, introduce, or amend their laws, regulations, and measures to promote the public interest in sectors of vital importance to their socio-economic and technological development as long as it consists with the provision of the agreement. This article is very important because it seems to allow the member to implement and introduce new mechanisms to counter with the problem of TRIPs with regards to bio-prospecting problem if the member of the WTO can show the evidence to support the rationale to formulate, introduce, or amend their laws, regulations, and measures to promote the public interest in sectors of vital importance to their socio-economic. In the other words, the member countries who want to use this article, must be able to show that the bio-prospecting problem has caused the loss of benefit arising out of biological resources in which these biological resources, under the principle of international, shall belong to the country who own the biological resource and thus the benefit arising out of the monopoly protection given by the patent law to the product/ process derived of the biological resources shall partly be shared between the innovator and the owner of biological resources. This article might be the only article with a support of the article 7 that can be used to bring a rational to introduce a tool to deal with the problem of bio-prospecting. However, the key point of this article that might be an obstacle of the reinterpretation of this article is at the last part of it which is "as long as it consists with the provision of the agreement". The provision that can use the last part of the article 8 of the TRIPs agreement to obsolete the rationale of reinterpreting article 8 is the article 27.1[173] which clearly states that patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. This means that TRIPs allows it member to formulate, introduce, and amend their law on whatever reasons but those formulation, introduction, and amendment must not obstruct to the right of the innovator within the article 27.1 of the TRIPs agreement. However, if the developing happens to use this provision to reinterpret the TRIPs agreement, then the developed country that loses the interest of reinterpretation might bring the case to the panel to clarify this point. This thesis sees, by that time, the

173 ……subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

panel or the appellate body will have to weight up the cost and benefit of using this interpretation for the problem of bio-prospecting.

4.2.1.3 Article 27.2

> Article 27(2): Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre* public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

This article allows the member to exclude product and process from patentability inventions in order to protect *ordre public* or morality including to protect human, animal or plant life or health or to avoid serious prejudice to the environment. It should be noted here that the "environment" also refers to the "surrounding objects, region, or conditions, especially circumstances of life of person or society"[174]. So if the member of the WTO can provide evidence to support that the patent grant for the product and process derived of the biological resources has caused a negative impact to human, animal or plant life or health or to avoid serious prejudice to the environment., then article 27.2 could be used as an reason to reinterpret the TRIPs agreement. It is proposed that the concepts of *ordre public* and morality may be used as an exception to reinterpret the TRIPs in order to balance the TRIPs agreement and the issue of sovereign rights of state through the introduction of mechanisms to counter with the problem of bio-prospecting. However, first it is necessary to consider the meaning of *ordre public* and morality?

4.2.1.3.1 *Ordre public*

Ordre public derived from the French law. It has been defined as a protection of any activities or policies or measures that might be illegal or morally wrong or contrary to public policy in one country in order to prevent any grant such activities which could be exploited in other countries and it can be said as the production of the

174 Houghton Mifflin Company, "The American Heritage Dictionary of the English Language", (Fourth Edition 2000)

public policy[175]. The European Patent Office had defined the word *ordre public* in the case T19/90 (the Oncomouse case[176]) as the protection of public security and the physical integrity of individuals in society, which includes the protection of the environment. Matthias Herdegen has defined the *ordre public* "is an ethical minimum to purports a fair distribution of regulatory powers and to the prerogative of national parliament to turn societal value judgments into binding rules"[177]. The European Court of Justice recently also emphasized the necessary discretion of Member States and their organs when applying the ethical exception as can be seen as follows[178]:

> "However, that scope for manoeuvre is necessary to take account of the particular difficulties to which the use of certain patents may give rise in the social and cultural context of each member state, a context which the national legislative, administrative and court authorities are better placed to understand than are the Communities authorities. That sort of provision, which allows patents to be refused where there, is a threat to *ordre public* or morality is, moreover, a well-known one in patent law and appears *inter alia* in the relevant international legal instruments, such as the EPC."

4.2.1.3.2 Morality

On the moral issue, the issue of morality has increasingly been with the patent law since the development of technology particularly biotechnology. Morality has been defined as principles of right and wrong in behaviour[179]. It is the degree of conforming to a standard of what is right and good[180] and it implies conformity to established sanctioned codes or accepted notions of right and wrong[181]. Under the EC and UK Patent Act of 1977, it states that "a patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or

175 Duncan Curley and Andrew Sharples; "Patenting Biotechnology in Europe: The Ethical Debate Moves on",, European Intellectual Property Review(2002): Editorial p 6

176 Harvard/ Onco-mouse (2003) OJEPO 473

177 Matthias Herdegen, " Patents on Parts of the Human body: Salient Issues under EC and WTO Rule"; the Journal of World Intellectual Property Vol.5 No. 2 March (2002) p.153

178 T.M. Spranger,,"Ethical Aspects of Patenting Human Genotypes According to EC Biotechnology Directive", 31 International Review of Industrial Property and Copyright Law, (2000), 373, Case C-377/98 p.378

179 Merriam-Webster Online Dictionary available at (http://www.m-w.com) (8 February 2006)

180 The Concise Oxford Dictionary p. 637

181 Merriam-Webster online Dictionary available at (http://www.m-w.com) (8 February 2006)

morality". The importance of morality issue in patent law seems to be weighting up between benefit to human and the suffering or the impact of the invention to the tester, environment or even to mankind[182]. Therefore, it would be inadmissible that patent office grant patents to any kind of invention, without any consideration of morality[183]. However, many would argue that moral and public policy objectives should not play a part of granting a patent[184]. Nonetheless, the EPC and UK Patent Act of 1977 have affirmed its ground on the relevance of ethical considerations such as breaching public peace or social order or seriously prejudice the environment. In addition, the biotechnology directive also provides some specific type of inventions that are not patentable such as processes for cloning human beings, use of human embryos for industrial or commercial purposes and etc.

From the above two definitions, if the member of the WTO would like to use article 27.2: *Ordre Public* and morality as one of the reasons to introduce the mechanism to counter the problem of bio-prospecting as a reinterpretation of TRIPs agreement, then the member of the WTO must be able to explain to the other members of the WTO how the problem of bio-prospecting is illegal, *ordre public* or morally wrong or contrary to public policy in the member country. From the definition of *ordre* public and morality, the TRIPs does recognize the public policy to be a tool to determine the appropriateness of what is right and wrong for the patentable subject matter. As a consequence, if the member countries can legitimately provide and prove that such exploitation of a product or process (bio-prospecting) causes the ordre public or is morally conducted or obtained through the use of public policy (in the form of legislation) in their countries then, such invention could be prohibited and should not be granted a patent protection or to a lesser extent, it should be a justification to allow the member of the WTO to equip the mechanisms to ensure the balance of the rights between the innovator provided by article 27.1 of the TRIPs

182 Harvard/ Onco-Mouse (1990) EPOR 4

183 See Alberto Bercovitz, Panel Discussion on Biotechnology, in Kraih Hill and Laraine Morse (Eds.), "Emergent Technologies and Intellectual Property. Multimedia, Biotechnology & Others Issues", ATRIP, CASRIP Publications Series No. 2, Seattle (1996), p. 53.

184 Nott (1933) E.I.P.R. p. 85-86

agreement and the owner of biological resources under the principle of international law[185].

However, as mentioned that the prohibition of patent protection for the product/ process derived of biological resources would not be recommended in this thesis because at certain extent, the IPRs does still provide an incentive for inventor to develop product/ process but using article 27.2 as one of the rationales to introduce a tool to deal with the problem of bio-prospecting under the TRIPs agreement would be an option. In addition, each individual member of the WTO shall have their own definition of the *ordre public* and morality or provide a list of exploitation through a public policy since the definition may be varied upon socio-economic background and conditions. The country such as Thailand must show to the other members of the WTO that the problem of bio-prospecting is *ordre public* and morally wrong through the sound public policy and such public policy must come from a sound and systemic way.

Looking from question whether the agreement provide any rooms for the developing nations to reinterpret TRIPs, it can be seen that the TRIPs agreement does give some room for its member to justifiably to introduce the condition to counter the provisions of the TRIPs agreement through the use of article 7, 8, and 27.2. However, the members of the WTO who want to use these articles; they must provide a good rationale, statistical data, and sound and systemic public policy or even democratic legislation to ensure that the reasons for using these articles are evidently supported.

4.2.2. Amendments

The other option for using TRIPs to address the problem of bio-prospecting is amendment. The amendment is technically an easy option to address the problem because it goes directly to answer the problem. However, the amendment is a difficult option to implement because there are a lot of disagreement of how to address the problem of bio-prospecting. It can be said that a group of country who

185 In the EPO, see Howard Florey/Relaxin T741/91 [1995] EPOR 541, Plant Genetic Systems: Glutamine Synthesise Inhibitors T356/93 [1995] , EPOR 357,Harvard/Onco-mouse [1990] EPOR 4 (original hearing before the ED), , T19/90 [1990] EPOR 501 (TBA) (appeal hearing), [1991] EPOR 525 , (remittal hearing before the ED) ,R. v. Leland Stanford/Modified Animal [2002] EPOR 2,Wisconsin Alumni Research Foundation, [2009] E.P.O.R. 15, paras 15-31

benefit from the way the law was written still do not want to amend the agreement whereas the countries who do not benefit want to change it. The most important is that the amendment of the TRIPs agreement can be made only when the decision come in the term of consensus. In addition, the amendment option might not be suitable in a sense that, presently, there are many problems raised under the TRIPs agreement and possibly in the future, therefore, this thesis is of the opinion that the TRIPs agreement shall not be a place to be amended every time when there is a problem.

4.3 How the problem of bio-prospecting under TRIPs agreement has been discussed internationally

For the problem of bio-prospecting, there were several discussions made both at the international forums. At the international forum, it can clearly be seen below that there are a lot of disagreements at the international forums for example between the members of the WTO at the TRIPs council. This thesis will show examples of the communications at the TRIPs Council discussing how to address the problem of bio-prospecting in respect to the patent law. The TRIPs council has been discussed whether the mechanisms to deal with the problem of bio-prospecting shall be dealt inside or outside the scope of patent law.

4.3.1 TRIPs

The review of the article 27 of the TRIPs agreement began in 1999. The topics of the article 27 raised in the TRIPs council include how to apply the existing TRIPS provisions on whether or not to patent plants and animals, the meaning of effective protection for new plant varieties, how TRIPs handle moral and ethical issues, how to deal with the commercial use of traditional knowledge and genetic material by those other than the communities or countries where these originate, especially when these are the subject of patent applications, and how to ensure that the TRIPS Agreement and the UN Convention on Biological Diversity (CBD) support each other. In addition, in the year 2001, the Doha Declaration made it clear in paragraph 19 that the TRIPs Council should also look at the relationship between the TRIPs agreement and the CBD, the protection of traditional knowledge and folklore

and on disclosing the source of biological material and associated traditional knowledge. The Council shall be guided by the TRIPS Agreement's objectives (Article 7) and principles (Article 8), and must take development issues fully into account.

With regards to the problem of bio-prospecting, the discussions at the TRIPs Council largely deal with the disclosure of the source of genetic resources and traditional knowledge. In the TRIPs council, the members of the Council have different opinions on the issue of disclosure. The question is not about they disagree on whether the problem of bio-prospecting is existed or whether the disclosure requirements which are PIC and BS are two most effective tools to deal with the problem of bio-prospecting but the main questions at the Council is whether the CBD which suggests the mechanisms such as the PIC and BS and TRIPs are applied in a mutually supportive way and if it does, then these two mechanisms: PIC and BS shall be introduced inside the scope of patent law or outside the scope of patent law. In the TRIPs Council, there are opinions with regards to the TRIPs and CBD as follows:

4.3.1.1 Whether or not the TRIPs and CBD are applied in a non-conflicting and mutually supportive way. The member of the TRIPs Council sees the first question with two findings as follows186:

4.3.1.1.1 There is no conflict between the two Agreements[187] and member of the WTO can implement the two in a mutually supportive way through national measures[188].

4.3.1.1.2 There is inherent conflict between the TRIPs Agreement and CBD, therefore, the TRIPs needs to be amended to remove such conflict. There are two reasons for the above argument. The first reason is that the TRIPS Agreement should

186 IP/C/W/368/ REV.1 The relationship between the TRIPs Agreement and the Convention on Biological Diversity : World Trade Organization; 8 Feb 2006, p. 4

187 Australia, IP/C/W/310, IP/C/M/47, para. 55, IP/C/M/46, para. 62, IP/C/M/40, paras. 100-101, IP/C/M/38, para. 236, IP/C/M/36/Add.1, para. 222; Canada, IP/C/M/47, para. 66, IP/C/M/40, para. 115, IP/C/M/37/Add.1, para. 232, IP/C/M/36/Add.1, para. 229; Japan, IP/C/W/236, IP/C/M/47, para. 69, IP/C/M/39, para. 137, IP/C/M/26, para. 77, IP/C/M/25, para. 93; Korea, IP/C/M/46, paras. 52-53, IP/C/M/42, para. 104; United States, IP/C/W/434, IP/C/W/257, IP/C/W/209, IP/C/W/162, IP/C/M/43, para. 55, IP/C/M/42, para. 109.

188 United States, IP/C/W/209, IP/C/W/162, IP/C/M/46, para. 24, IP/C/M/25, para. 71.

ensure all biological resources, not only for certain genetic resources and plant varieties, is not inconsistent with the sovereign rights of countries over their genetic resources as provided for in the CBD[189]. For the second reason, the TRIPS Agreement shall be written in respect with the provisions of the CBD, including those relating to prior informed consent and benefit sharing.[190]

4.3.1.2 For the second question of whether the PIC and BS shall be introduced inside the scope of patent law or outside the scope of patent law.There are three proposals that have been suggested as can be seen as follows:

4.3.1.2.1 The TRIPS Agreement should be amended to incorporate certain requirements of the CBD in particular the disclosure requirement of the patent application whether the sources and country of origin of any biological resources used in invention obtain the PIC from the competent authority and enter into BS scheme[191] or that they followed national legal requirements[192]. Leading proponents of this view include Peru, Thailand, and Columbia. Peru stated very clearly in the Council that

189 African Group, IP/C/W/404, IP/C/W/206, IP/C/W/163, IP/C/M/40, paras. 76-79; Kenya, IP/C/M/47 para. 68, IP/C/M/36/Add.1, para. 233, IP/C/M/28, para. 144.

190 African Group, IP/C/W/404, IP/C/W/206, IP/C/W/163; Brazil, IP/C/W/228, IP/C/M/48, para. 37, IP/C/M/29, paras. 146 and 148; IP/C/M/28, para. 135, IP/C/M/27, para. 122; Brazil et al, IP/C/W/429/Rev.1, IP/C/W/356; Colombia, IP/C/M/46, para. 57, IP/C/M/36/Add.1, para. 209; Ecuador, IP/C/M/47, para. 49, IP/C/M/25, para. 87; EC, IP/C/W/383, IP/C/W/254, IP/C/M/48, para 63, IP/C/M/39, para. 127, IP/C/M/37/Add.1, para. 226, IP/C/M/35, para. 233; India, IP/C/W/198, IP/C/W/195, IP/C/M/48, para.52, IP/C/M/36/Add.1, para. 212, IP/C/M/30, para. 169, IP/C/M/24, para. 81; Indonesia, IP/C/M/47, para. 51, IP/C/M/36/Add.1, para. 217; Peru, IP/C/W/447, IP/C/M/48, paras. 18-19; Thailand, IP/C/M/48, para. 61, IP/C/M/25, para. 78; Turkey, IP/C/M/47, para. 63, IP/C/M/27, para. 132; Venezuela, IP/C/M/40, para. 102, IP/C/M/36/Add.1, para. 208, IP/C/M/32, para. 136, IP/C/M/28, para. 165.

191 Andean Community, IP/C/M/37/Add.1, para. 231; Brazil et al, IP/C/W/429/Rev.1, IP/C/W/403, IP/C/W/356; Brazil, IP/C/W/228, IP/C/M/49, para. 154, IP/C/M/46, para. 81, IP/C/M/42, para. 101, IP/C/M/39, para. 126, IP/C/M/38, para. 230, IP/C/M/37/Add.1, para. 237, IP/C/M/36/Add.1, para. 219, IP/C/M/33, para. 121, IP/C/M/32, para. 128, IP/C/M/29, paras. 146, 148, IP/C/M/28, para. 135, IP/C/M/27, para. 122; China, IP/C/M/47, para. 57, IP/C/M/37/Add.1, para. 229, IP/C/M/36/Add.1, paras. 227-228; Colombia, IP/C/M/46, para. 57, IP/C/M/42, para. 119, IP/C/M/40, para. 121, IP/C/M/38 para. 239; Ecuador, IP/C/M/47, para. 49, IP/C/M/25, para. 87; India, IP/C/W/198, IP/C/W/195, IP/C/M/49, paras. 86-90 and 134-146, IP/C/M/45, para. 25, IP/C/M/42, para. 113, IP/C/M/40, paras. 81-82; IP/C/M/36/Add.1, paras. 212 and 214, IP/C/M/30, para. 169, IP/C/M/24, para. 81; Indonesia, IP/C/M/49, para. 159, IP/C/M/47, para. 51, IP/C/M/36/Add.1, para. 217; Kenya, IP/C/M/47, para. 68, IP/C/M/46, para. 67, IP/C/M/42, para. 114, IP/C/M/40, para. 107, IP/C/M/37/Add.1, para. 239, IP/C/M/36/Add.1, para. 233, IP/C/M/28, para. 144; Pakistan, IP/C/M/36/Add.1, para. 211; Peru, IP/C/M/40, para. 84, IP/C/M/36/Add.1, para. 203; Philippines, IP/C/M/47, paras. 79-80; Thailand, IP/C/M/42, para. 105, IP/C/M/25, para. 78; Turkey, IP/C/M/47, para. 63, IP/C/M/27, para. 132; Venezuela, IP/C/M/40, para. 102, IP/C/M/36/Add.1, para. 208, IP/C/M/32, para. 136, IP/C/M/28, para. 165.

192 African Group, IP/C/W/404, IP/C/W/206, IP/C/W/163, IP/C/M/40, paras. 76-79.

the inclusion of the disclosure requirement and benefit sharing[193] in the criterion of patentability is necessary because Peru did not see that the voluntary requirement would help to deal with the problem of bio-prospecting in the long term, therefore, the revision of TRIPS addressing the issue of incorporating the requirement of legal provenance and disclosure of origin under the exclusions from patentability and under the conditions required for patent applications (Articles 27 and 29, respectively) is necessarily important as can be seen as follows:

> "…Peru, which advocate mandatory inclusion so as to guarantee the more efficient and secure implementation of TRIPS itself and generate a situation of positive synergy between TRIPS and the Convention on Biological Diversity (CBD).[194]"

Bolivia, Brazil, Colombia, Cuba, Dominican Republic Ecuador, India, Peru and Thailand also saw the disclosure requirement and benefit sharing should also be compulsory included in the patent law because they saw that a requirement of disclosure of evidence of benefit-sharing would operate as an important supplementary measure and a necessarily incentive for patent applicants to comply with the prevalent laws and practices of the countries of origin of the genetic resources in accordance with the objectives and norms of the CBD[195]. Norway supports the amendment of the TRIPS Agreement to include a mandatory obligation to disclose the origin of genetic resources and traditional knowledge in patent applications. Norway has clearly stated that "an obligation under the TRIPS Agreement to disclose the origin of genetic resources when applying for patent protection would ensure transparency as regards the origin of biological materials that

193 The PIC and Benefit Sharing scheme will be explained in details in the next chapter.

194 An important milestone in the WTO context is the Doha Declaration (adopted on 14 November 2001 at the Fourth WTO Ministerial Conference), in paragraph 19 of which Ministers agree to instruct "the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension." It is also important to emphasize the efforts and manifest interest of countries like Peru in making progress on implementation issues, as provided in paragraph 12 of the Declaration, which recognizes "implementation-related ... concerns", "implementation problems faced by Members", and hence the necessity that "outstanding implementation issues shall be an integral part of the Work Programme" established by Members.

195 IP/C/W/470 Submission in response to the Communication from Switzerland. A Communication from Communication from Bolivia, Cuba, Ecuador, India, Sri Lanka and Thailand, World Trade Organization; 21 March 2006

are to be patented."[196] It should be noted that these countries are the country where they also see that there is inherit conflict between the TRIPs agreement and the CBD. Switzerland and the EU also proposed that the Regulations of the PCT of WIPO should be amended to require patent applicants to disclose the source of biological resources[197] and also proposed its position to enable the national patent legislation to require patent applicants to declare the source of genetic resources and traditional knowledge in patent applications. The patent application should mandatory require to disclose the origin of biological resources at the national, regional and international levels, with penalties for non-compliance outside the patent system[198]. The disclosure and benefit sharing requirements shall be made through national legislation and contractual arrangements based on the legislation[199]. For the reasons of why this option is a choice because, for example, the United States[200] has argued that the Convention on Biological Diversity's objectives on access to genetic resources, and on benefit sharing, could best be achieved through national legislation and contractual arrangements based on the legislation, which could include commitments on disclosing of any commercial application of genetic resources or traditional knowledge. For example, patents can be instrumental in the sharing of benefits and the conservation of biological diversity based on voluntary contracts; the requirements of the patent system material to patentability and inventor-ship can help prevent bad patents; the control over production and distribution given to patent owners and their licensees can facilitate the sharing of technology; and the protection of undisclosed information could help the implementation of bio-safety and benefit-sharing rules. Benefit sharing provisions of the CBD can also be implemented through governmental fund-granting activities[201]and the financial mechanism provided for under Articles 20 and 21 of the CBD[202]. The view has been expressed

196 IP/C/W/473 The Relationship between the TRIPs and the CBD and the protection of traditional knowledge: Amending the TRIPS agreement to introduce an obligation to disclose the origin of genetic resources and traditional knowledge in patent applications; 14 June 2006

197 Switzerland, IP/C/W/433, IP/C/W/423, IP/C/W/400/Rev.1, IP/C/M/49, para. 115, IP/C/M/46, para. 22, IP/C/M/45, paras. 47-48, IP/C/M/44, para. 25, IP/C/M/42, paras. 97 and 99, IP/C/M/40 para. 71.

198 EC IP/C/W/383, IP/C/M/49, paras. 123-124, IP/C/M/46, paras. 43-49; Norway, IP/C/W/293, IP/C/M/47, paras. 64-65

199 This proposal is purposed by the U.S., Japan, and etc.

200 United States, IP/C/W/434, IP/C/W/257, IP/C/M/30, para. 154.

201 Japan, IP/C/W/236.

202 United States, IP/C/W/257

that Members appear to share several broad policy objectives, including those of ensuring authorized access to genetic resources, achieving equitable sharing of benefits arising from the use of traditional knowledge and genetic resources and preventing the grant of erroneously issued patents, and that the most effective means to achieve these objectives is through tailored national solutions, including contracts, to meet practical concerns and actual needs.[203] Japan also saw that putting the disclosure requirement as criteria of patentability would not help with the problem of prior art and putting the disclosure requirement such as the Prior Informed Consent outside the scope of patentability as suggested in the Bonn Guideline would be more appropriated[204].

Looking from the above countries' positions with regards to disclosure requirement, it can be seen that there are two groups divided with regards to this issue. The first group would be the developing countries who saw that compulsory disclosure requirements which are the PIC and BS in the patent law under the TRIPs would address the problem of bio-prospecting. This group who also has a lot of biological resources would directly benefit from this amendment. For the second group would be the US and Japan, this group who have a lead in technology would not like to see the PIC and BS as a compulsory requirement under the patent law because they don't see it is a place where the mechanism should be put to. They would want to see them put in the national legislation or in the other words, through the voluntary basis. It should be noted here again that the amendment of the TRIPs agreement must be in the form of consensus so the possibility of amending the TRIPs would still be a difficult option at this point of time.

4.4 Conclusion

In order to find out how Thailand can legally deal with the problem of bio-prospecting, it is necessary to examine the articles of the TRIPs agreement. It can be understood that the TRIPs articles is very rigid and have been a problem for the

203 Australia, IP/C/M/46, para. 62; United States, IP/C/W/434, IP/C/W/257, IP/C/W/209, IP/C/M/46, paras. 30-32, IP/C/M/43, para. 55, IP/C/M/42, para. 109, IP/C/M/40, paras. 122 and 124, IP/C/M/39, paras. 129-130, IP/C/M/38, para. 234, IP/C/M/37/Add.1, paras. 234-235 and 250, IP/C/M/36/Add.1, para. 231.

204 IP/C/W/472 The Patent System and Genetic Resources : World Trade Organization; 13 June 2006

problem of bio-prospecting in the past few years. This chapter has analyzed how to deal with the problem of bio-prospecting under the TRIPs agreement. The first option is to find exceptions from the articles of the TRIPs agreement and second option is to amend the TRIPs agreement. This thesis would like to conclude that the amendment option is a very good option because it directly addresses the problem of bio-prospecting but the problem of this option is it is difficult to get a consensus at the council since there are still a lot of disagreements between the members of the TRIPs Council of how to address the problem of bio-prospecting as can be seen from the second section of this chapter. Therefore, the first option is the better option in practice.

In order to use this option, it is proposed that Articles 7, 8, and 27.2 could be used as a rationale to introduce a tool to deal with the problem of bio-prospecting without touching the articles of the TRIPs agreement. In the next chapter, therefore, formal requirements will be introduced that could be used to counter the problem of bio-prospecting. These formal conditions are Prior Informed Consent (PIC) and Benefit Sharing Schemes (BS). These two conditions will be able to help any countries to be able to control the access and use of biological resources. Before introducing the conditions, it will be explained that States have sovereign rights to introduce any conditions or tools to deal with the problem of bio-prospecting. It will then be argued that the best place to put the conditions is though a new legislation in cooperate with the reinterpretation of the article 7, 8, and 27.2 of the TRIPs agreement. The new legislation will be equipped with conditions and tools in order to control the access of biological resources by stopping the inventor taking away the biological resources before they even apply for the patent protection. As a consequence, this option is a way to address the problem of bio-prospecting without touching on the criteria of patentability of the TRIPs agreement.

Chapter 5: Sovereignty of States and the Use of Formal Conditions

The previous chapter concluded that there is a way to deal with the problem of bio-prospecting through an interpretation of the TRIPs agreement by introduction of a new legislation equipped with the formal conditions. This chapter will be divided into two sections. The first section will explain the role of State sovereignty and that States can legitimately introduce the formal conditions to cope with the problem of bio-prospecting. The second section will introduce and analyze the formal conditions. It will explain why the conditions of Prior Informed Consent (PIC) and Benefit Sharing (BS) are appropriate for dealing with the problem of bio-prospecting.

5.1 State Sovereignty

The concept of State sovereignty can be seen in the Montevideo Convention on the Rights and Duties of States 1933 which articulates the elements of statehood in international law. The article of the Convention provides: "The state as a person of international law should possess the following qualifications: a) a permanent population; b) a defined territory; c) government; d) capacity to enter into relations with other states. The importance of state is that the states are central to the international legal system which is one of the core principles of international law: state sovereignty. In international law, sovereignty is the legitimate exercise of power by a state. The state sovereignty has been seen as the absolute ability of state to decide and determine for her on any matter including on its territory and natural resources. Under the principle of international law, the state has the sovereign rights over their own territories including their natural resources.

Even though, before 20th century, the international law has not explicitly been written about the sovereign rights of state over her property but it has clearly understood that the state has been practiced its own power to decide and determine over her properties including her territories both land, sea, and her natural resources. One of the first international law's documents that recognize the rights of the state could be seen in the Charter of the United Nations (1945) which recognizes the rights

of the state to have her self-determination[205] and her sovereignty over her natural resources. After 1945, there were several identifiable international norms that showed the state has her rights over their natural resources. Those include the General Assembly Resolution of 1962 on Permanent Sovereignty over Natural Resources proclaiming that "the right of peoples and nations to permanent sovereignty over their natural wealth and resources must be exercised in the interest of their national development and of the well being of the people of the State concerned" and the UN: the Charter of Economic Rights and Duties of States (1974) asserting that "Every state has and shall freely exercise full permanent sovereignty including possession, use and disposal, over all its natural resources". The 1974 Charter had also recognized the states have her rights over the natural resources and economic activities[206]. Other visible norms can also be seen from the Declaration on the establishment of A New International Economic Order of the 1974 General Assembly[207].

Prior to Declaration of 1974, the United Nations held the first conference addressing the international environmental issues call the United Nations Conference on the Human Environment in Stockholm. Even though there was no treaty signed at the conference but there were 109 recommendations and a Declaration of 26 Principles adopted. The key principles in the Declaration which recognized the sovereignty of state over natural resources are in the Principle 21 as can be read as follows:

> "States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction (Principle 21)"

205 Charter of the United Nations (1945)/ Art 1.2 and 2.1

206 Charter of Economic Rights and Duties of States (1974)/ Art 2:1 of Chapter two

207 " 4. The new international economic order should be founded on full respect for the following principles:

d) The right of every country to adopt the economic and social system that it seems the most appropriate for its own development and not to be subjected to discrimination of any kind as a result:) Full permanent sovereignty of every State over its natural resources and all economic activities. In order to safeguard these resources, each State is entitled to exercise effective control over them and their exploitation with means suitable to its own situation, including the right to nationalization or transfer of ownership to its nationals, this right being an expression of the full permanent sovereignty of the State. No State may be subjected to economic political or any other type of coercion to prevent the free and full exercise of this inalienable right.

An example of an international agreement that has legal effect in the international community which recognizes the right of States Sovereignty is the United Nations Convention on the Law of the Sea in which more than 160 countries had rectified this Convention. This Convention was signed to recognize the state sovereignty over her territory[208] and in response to the problem of over exploitation of natural resources and equitable and efficient use of natural resources[209]. This Convention has explicitly drawn the line of territorial area of the states to exploit her natural resources which indicate the territorial right of the state[210].

The other important international agreement which recognizes sovereign rights of States over their natural resources is the Convention on Biological Diversity (CBD) in which 190 countries have rectify this convention[211] (whereas only 151 countries are member to the WTO[212]). The CBD could be considered as the first convention that made the awareness of member states on the issue of sovereignty of the states over biological resources. The objectives of the CBD are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding[213]. The preamble of the Convention reaffirms that States have sovereign rights over their own biological resources. In the text agreement of the Convention, it specifically recognizes the sovereign rights of the states to exploit and conduct their policy over their natural resources[214].

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208 Article 193: Sovereign right of States to exploit their natural resources: States have the sovereign right to exploit their natural resources pursuant to their environmental policies and in accordance with their duty to protect and preserve the marine environment

209 David Hunter, James Salzman, Durwood Zaelke, International Environmental Law and Policy, (Second Edition), p. 657

210 Article 2: Legal Status of the territorial sea, of the air space over the territorial sea and of its bed and subsoil

211 Parties to the Convention on Biological Diversity / Cartagena Protocol on Biosafety, Convention on Biological Diversity, www.biodiv.org/world/parties.asp (9 March 2009)

212 Information available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (9 March 2009)

213 Convention on Biological Diversity / Art 1

214 Convention on Biological Diversity / Art 3 "States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction."

Therefore, recognizing the sovereign rights of state in the text agreement of the CBD, as mentioned, creates a major states attention of their ownership, use and control of genetic resources unilaterally and multilaterally. For the unilateral action, this thesis will show in the next chapter that there are many states which parties to the CBD has drafted and enacted the legislation to protect the ownership of their natural resources right after they rectified the convention. For multilateral action, the previous chapter has shown that there are talks at the international forum such as the TRIPs council and WIPO forum to discuss of how the problem of bio-prospecting could be addressed or rewritten in the international forum such as at the TRIPs council.

5.2 Formal Conditions

In order to ensure that the sovereignty of state is internationally recognized for the problem of bio-prospecting, there are many ways in which the state can protect themselves such as through the unilateral action or act on her own, the multilateral agreement or through the WTO or WIPO, or the bilateral agreement such as the Free trade agreement. For the multilateral and bilateral agreement, there are evidences as can be seen in the previous chapter that there have been a slow process of negotiating on the issue of bio-prospecting between the developed and developing nations. Therefore, unilateral action might be the option at this time. The country should find ways to legitimately control the access and use of biological resources in order to address the problem of bio-prospecting. This chapter would like to introduce the legitimate conditions to be used to protect her sovereign interests over natural resources. These requirements which can be used to uphold the sovereignty of state over natural resources are Prior Informed Consent (PIC) and Benefit sharing (BS).

5.2.1 Prior Informed Consent (PIC)

The first condition is called “Prior Informed Consent” (PIC). PIC is a condition for a recipient party to be notified and give her consent of any action done by the other party to ensure that the states have their rights to uphold their decision. The states should have the right to finalize the decision as a result of action done by

the other party in their country. Under international law, the state shall not allow to conduct any activities within their territories without regard for the rights of other states as expressed to the maxim "*sic utere tuo, ut alienum non laedas"* or "principles of good neighbourliness"[215]. The principle of Prior Informed Consent has been established as a condition to ensure that the above maxim is followed. PIC has been introduced as one of the states' commitment to assure that the activity of any state would not affect the other state. It is to believe that it would be of best interest for both parties if one party could notify and consult her activities before doing anything that might have an impact to the others. It could also be said that this principle has derived largely from the combination of a customary international law: *a duty to notification, consent, and consultation* and the recognition of the sovereignty of the state over their territory with regards to the injury that may rise. The PIC principle can also be seen in, for example, the Principle 6 of 1978 UNEP Principles on Shared Natural Resources[216] or the Article 19 of the Rio Declaration[217].

Nowadays, many international agreements have put the PIC in the article of international agreement, including the following international agreements in which PIC is a main condition that has been used to serve the objectives of agreement:

5.2.1.1 The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)

The CITES applies the PIC as a tool to prevent the listed species becoming extinct[218]. The Convention requires its member exporting countries to give the prior informed consent of the listed species by presenting the export or re-export certificate

215 P.W. Birnie and A.E. Boyle, International Law and the Environment, 2nd edition, p. 109

216 It is necessary for every State sharing a natural resource with one or more other States:1. to notify in advance the other State or States of the pertinent details of plans to initiate, or make a change in, the conservation or utilization of the resources which can reasonably b expected to affect significantly the environment in the territory of the other State or States; and 2. Upon request of the other State or States, to enter into consultations concerning the above mentioned plans.

217 States shall provide prior and timely notification and relevant information to potentially affected States on activities that may have a significant adverse trans-boundary environmental effect.

218 CITES Convention /Art II: Fundamental Principle

for movement of listed species as can be seen in the article 3: Regulation of Trade in Specimens of Species Included in Appendix I[219].

5.2.1.2 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal

The Basel Convention was designed for two main reasons which are to avoid risk that can damage and growing threat for human health and environment as a result of hazardous wastes and other wastes and transboundary movement[220]: During the negotiation periods, members of the convention had come up with a condition which was the PIC to deal with the transboundary movement of hazardous wastes. The convention requires the exporting state to ask a permission of the importing state with a written note before any importation of any hazardous wastes to the importing state as can be seen in the article 6: Transboundary Movement between Parties[221]. In addition, if the member of the convention does not apply the PIC rule with the transboundary movement of hazardous wastes, then such trade will be considered to

219 CITES Convention/ Art 3: 2. : The export of any specimen of a species included in Appendix I shall require the prior grant and presentation of an export permit. An export permit shall only be granted when the following conditions have been met: (a) a Scientific Authority of the State of export has advised that such export will not be detrimental to the survival of that species; (b) a Management Authority of the State of export is satisfied that the specimen was not obtained in contravention of the laws of that State for the protection of fauna and flora; (c) a Management Authority of the State of export is satisfied that any living specimen will be so prepared and shipped as to minimize the risk of injury, damage to health or cruel treatment; and (d) a Management Authority of the State of export is satisfied that an import permit has been granted for the specimen

Article 3:3: The import of any specimen of a species included in Appendix I shall require the prior grant and presentation of an import permit and either an export permit or a re-export certificate. An import permit shall only be granted when the following conditions have been met: (a) a Scientific Authority of the State of import has advised that the import will be for purposes which are not detrimental to the survival of the species involved;(b) a Scientific Authority of the State of import is satisfied that the proposed recipient of a living specimen is suitably equipped to house and care for it; and (c) a Management Authority of the State of import is satisfied that the specimen is not to be used for primarily commercial purposes.

220 Preamble of the Convention

221 Article 6.1: The State of export shall notify, or shall require the generator or exporter to notify, in writing, through the channel of the competent authority of the State of export, the competent authority of the States concerned of any proposed trans-boundary movement of hazardous wastes or other wastes. Such notification shall contain the declarations and information specified in Annex V A, written in a language acceptable to the State of import. Only one notification needs to be sent to each State concerned. Article 6.2: The State of import shall respond to the notifier in writing, consenting to the movement with or without conditions, denying permission for the movement, or requesting additional information. A copy of the final response of the State of import shall be sent to the competent authorities of the States concerned which are Parties.

be illegal traffic in which the exporter are required to take back the waste as can be seen in the article 9 of the convention[222].

5.2.1.3 Cartagena Protocol on Biosafety to the Convention on Biological Diversity

The Cartagena Protocol has recognized the principle of PIC as a condition to ensure and focus on trans-boundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity[223]. The PIC principle can be seen in articles 8 and 9 of the agreement. Article 8 (Notification) requires the exporter of a living modified organism to notify in writing to the party of import. Article 9 gives the Party of Import has her right to receive a receipt of a notification as consent to an international trans-boundary movement.

5.2.1.4 Convention on Biological Diversity (CBD)

The objectives of the CBD are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding[224]. In the Preamble of the CBD[225] and in Article 15:5 of the convention,

222 Article 9:1. For the purpose of this Convention, any trans-boundary movement of hazardous wastes or other wastes:(a) without notification pursuant to the provisions of this Convention to all States concerned; or (b) without the consent pursuant to the provisions of this Convention of a State concerned; or (c) with consent obtained from States concerned through falsification, misrepresentation or fraud; or (d) that does not conform in a material way with the documents; or (e) that results in deliberate disposal (e.g. dumping) of hazardous wastes or other wastes in contravention of this Convention and of general principles of international law shall be deemed to be illegal traffic.

Article 9:2 In case of a trans-boundary movement of hazardous wastes or other wastes deemed to be illegal traffic as the result of conduct on the part of the exporter or generator, the State of export shall ensure that the wastes in question are: (a) taken back by the exporter or the generator or, if necessary, by itself into the State of export, or, if impracticable, (b) are otherwise disposed of in accordance with the provisions of this Convention, within 30 days from the time the State of export has been informed about the illegal traffic or such other period of time as States concerned may agree. To this end the Parties concerned shall not oppose, hinder or prevent the return of those wastes to the State of export.

223 Cartagena Protocol/ Preamble

224 CBD/ Art 1

which deal with the accessibility to the genetic resources, states it clearly about the use of PIC for the accessibility of the member countries of the convention in order to recognize the sovereign rights over natural resources of the member states[226].

As a consequence, in the annual meeting: the Conference of the Parties 6 (COP), the parties agreed Decision VI/24 on access and benefit-sharing as related to genetic resources called " Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization" which requires the member States of the CBD to seek *informed consent prior* to access to genetic resources of the member countries, in conformity with Article 15, paragraph 5, of the Convention[227] on the voluntary basis in order to use the guidelines when developing and drafting legislative, administrative or policy measures on access and benefit-sharing, and contracts and other arrangements under mutually agreed terms for access and benefit-sharing and also to recognize that the guidelines are a useful first step of an evolutionary process in the implementation of relevant provisions of the Convention related to access to genetic resources and benefit-sharing[228]. As can be seen from the above explanation, it can be seen that the CBD has been considered to be the other convention which use the PIC as a condition to control the access and use of genetic resources in order to recognize the sovereignty of state.

5.2.1.5 The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

The latest international agreement that uses the PIC is the Rotterdam Convention on the Prior Informed Consent procedure for certain hazardous chemicals and pesticides in international trade. The objectives of this convention are to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment

225 States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

226 Article 15:5 Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

227 Decision VI/ 24 of the COP 6 of the CBD on 7-19 April 2002.

228 Biodiversity Convention , available at www.biodiv.org (4 March 2008)

from potential harm; and to contribute to the environmentally sound use of those hazardous chemicals, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties[229]. The Convention establishes a "Prior Informed Consent procedure," as a means for formally obtaining and disseminating the decisions of importing countries as to whether they wish to receive future shipments of specified chemicals and for ensuring compliance with these decisions by exporting countries as it can be seen in the article 12 on export notification. Importing countries shall also have a PIC duty to inform the exporting country whether to accept the products can be seen in the article 10 on obligations in relation to imports of chemicals. This can be seen as an indicator of the state sovereignty over their territories to decide whether the product shall be accepted in the territorial state.

5.2.1.6 The PIC and the problem of bio-prospecting

As it can be seen that the PIC has been used in different conventions for different objectives; however, there is one thing in common in these conventions which is the PIC has been used as an effective condition to ensure that the sovereignty of state and sovereign rights of states over their land and natural resources are recognized.

In order to deal with the problem of bio-prospecting, the PIC can be used to require any country or the researcher who bio-prospect the biological resources in another countries to receive a prior inform consent before taking the biological resources out of the country. The problem of bio-prospecting should be equipped with a condition such as PIC to ensure that the sovereignty of state is recognized. If the PIC were chosen as one of the effective conditions to deal with the problem of bio-prospecting, then, the requirement of the PIC to be imposed would be one of the desired conditions to deal with the problem of sovereignty rights over the natural resources with regards to bio-prospecting problem. However, it might be politically difficult to get a consensus at the TRIPs council to amend the TRIPs agreement because of the disagreement between the developed and developing nations; however,

229 the Rotterdam Convention/ Art 1

the PIC can still be considered as a desired condition unilaterally to control the access of biological resources along with the implementation of the TRIPs agreement.

5.2.2 Benefit Sharing

The Benefit sharing scheme is a condition to ensure that the benefit arising out of commercialization of the product and process are properly and mutually shared. With regards to the problem of bio-prospecting, there have been a lot concerns that the benefit arising out of the utilization of biological resources in particular from the bio-prospecting activities have been ignored when it shall be a compulsorily requirement or mutually shared and guaranteed between the owner of biological and bio-prospector especially/ innovator especially when it applies to an intellectual property protection.

The benefit sharing scheme for the problem of bio-prospecting was raised as a result of a shift of the political context of biological resources from "free to all, belong to none" to "sovereign rights of natural resources of state" which can largely seen on the adoption of the Convention on Biological Diversity (CBD). The CBD has recognized the sovereign rights of state over the natural resources and benefit sharing arising out of the natural resources through the stipulation in the article 8: In Situ Conservation (j)[230] , article 15: Access to Genetic Resources[231], and Article 19: Handling of Biotechnology and Distribution of its Benefits[232]. In the annual meeting: the Conference of the Parties 6 (COP), the party agreed to use the Benefit Sharing guidelines to develop and to draft legislative, administrative or policy measures on

230 Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing o the benefits arising from the utilization of such knowledge, innovations and practices.

231 Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19, where necessary, through the financial mechanism established by Article 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

232 Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

benefit-sharing and other arrangements under mutually agreed terms[233]. With regards to the types of benefit, the guideline has divided into two types of benefit which are Monetary[234] and Non-monetary[235] benefits.

5.2.2.1 Examples of Practicing of Benefit Sharing Scheme

In recent years, the benefit sharing scheme has been increasingly practiced with regards to bio-prospecting and benefit arising out of it between the private parties. These practices can be seen as follows:

5.2.2.1.1: India[236]

A field study in the tribal inhabited Western hat Region of Kerala, India, a team of scientists discovered a wild plant call "Trichophus Zeslanicus" or locally called by the Kani tribals as an "Arogyapacha". The specialty of this plant is to keep people energetic and agile.

The plant was experimented by the Ethnopharmacology Division of Regional Research Laboratory (RRL), Tropical Botanic Garden and Research Institute (TBGRI) in which confirmed the leaf of the plant contained various glycolipids and some other non-steroidal compounds with profound adaptogenic and immuno-enhancing properties. The TBGRI developed a drug from Arogyapacha and it was later named "Jeevni".

Many pharmaceutical firms contacted TBGRI for a license for the production of Jeevni. At the end, the manufacturing licenca of "Jeevni" was transferred to the Aryavaidya Pharmacy, Colmbatore Ltd. For a license fee of Rs. 10 lakhs for a period of 7 years with 2.0% royalty at ex-factory sales price. The TBGRI has also agreed to share 50% of the license fee and royalty with the tribal community.

233 www.biodiv.org (9 March 2008)

234 Monetary benefits may include, but not be limited to Access fees/fee per sample collected or otherwise acquired, Up-front payments, Milestone payments, Payment of royalties

235 Non-monetary benefits may include, but not be limited to Sharing of research and development results, Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the provider country, Participation in product development, Collaboration, cooperation and contribution in education and training, and etc.

236 R.V. Anuradha, Sharing with the Kanis: A case study from Kerala, India

5.2.2.1.2 Mali[237]

The case of Mali has arisen as a result of the discovery of wild rice from Mali. This wild rice contains *Oryza Longistaminata* which resistance to bacterial rice blight, one of the most serious rice diseases. The University of California at Davis (UCD) was able to isolated, cloned and patented the gene Xa21 of specimen of *Oryna longistaminata* in which the UCB obtained the specimen from the international Rice Research Institute in the Philippines. After the gene was patented, the UCD established the Genetic Resource Recognition Fund the share the benefit arising from the commercial utilization of the patented gene with the stakeholders as a fund will provide the fellowships to agriculture students and researchers from the Mali and stakeholders countries as a building capacity mechanisms for the donor country.

The CBD has clearly seen as a starting point for the development of benefit sharing scheme internationally. The above examples of the benefit sharing scheme can be used as a guideline for the country to develop their own benefit sharing mechanism which recognize the right of the traditional knowledge and the sovereign rights over the natural resources of the country as an additional condition before the grant of patent protection. Even though the benefit sharing has been practiced as can be seen in the given examples, however, the scheme has not been compulsorily added as criteria of patentability or compulsory requirement for the bio-prospecting activities. In order to ensure the sovereignty of state over natural resources is recognized, the PIC should be added as one of the criteria of patentability or in the legislation that control the use and access of biological resources.

5.3. Conclusion

In the conclusion, this thesis has pointed out that the international community has recognized the sovereignty of States over their biological resources through the treaty and customary law. However, the patent law under the TRIPs agreement which allow the biological resources to be patentable without receiving any formal consent

237 World Intellectual Property Organization, The Role of Intellectual Property Rights in the Sharing of Benefits arising from the use of Biological Resources and Associated Traditional Knowledge: Selected Case Studies; www.wipo.org

from the sovereign country has proven that the patent law under the TRIPs agreement has not recognized the sovereignty of state since the biological resources are not longer considered "free to all, belong to none" anymore. The formal conditions have been introduced in order to recognize the sovereignty of state over biological resources and directly deal with the problem of bio-prospecting. The PIC and BS scheme are internationally accepted as formal requirements in many international agreements. This thesis views that the PIC will ensure that any bio-prospecting activity will be done with the eye and ear of the country who own the biological resources. The benefit sharing scheme will also assure the recognition of sovereignty of state over biological resources and therefore the benefit arising out of utilization of biological resources will be fairly shared with the owner of biological resources.

The next chapter will introduce the concept of Social Impact Assessment (SIA). SIA will be introduced as a tool to guide and justify decisions made by the parties concerned when the formal conditions are to be used. It is argued that it is necessary for the parties concerned to be equipped with a tool to rationalize their decision in a wider and complete picture of the consequence of permitting the use of biological resources and maximizing benefit arising out of utilization of biological resources. The next chapter will therefore explain what SIA is and how can we use it with the problem of bio-prospecting.

Chapter 6: A Tool to Assist with the Use of Formal Conditions: Social Impact Assessment (SIA)

As previously explained, the problem of bio-prospecting directly and consequently affects human populations by altering the ways in which people live, work, play, relate to one another, organize to meet their needs and generally cope as members of society. It was recommended in previous chapter that the formal conditions of PIC and BS be used to deal with the problem of bio-prospecting. However, there is a question of how can we ensure that the authority concerned can properly and rationally deal with the problem or be able to use the formal conditions with efficiency and effectiveness. Social Impact Assessment or SIA may be used as a tool to quantitatively and qualitatively evaluate the benefits and costs either for directly dealing with the problem of bio-prospecting or from permitting bio-prospecting or to assess and quantify the benefit arising out of granting of access and utilization of biological resources. SIA would therefore equip the authority concerned with a safeguard condition or a tool to ensure that the conditions that use to control the access and use of biological resources in order to address the problem of bio-prospecting will bring a maximum benefit to the society when it applies for the commercial exploitation. In this chapter, it will be explained how SIA can be used in order to ensure the bio-prospecting problem has been addressed.

Before discussing how SIA could be of assistance to the problem of bio-prospecting, it is necessarily important to understand what Social Impact Assessment is in more detail.

6.1 NEPA[238] and SIA

The Congress passed the US National Environmental Policy Act of 1969 (NEPA) and was enacted on January 1st, 1970. NEPA required the federal and local government for any federal activities, which might have a significant effect on the quality of the human environment, to have an assessment to be undertaken. NEPA is a US environmental law that promotes the environmental quality and requires all

238 www.epa.gov (25 September 2010)

federal and government agencies to prepare Environmental Assessments (EAs) [239] and Environmental Impact Statements (EISs)[240]. NEPA came into force after the increase of environmental concerns including ecological and wildlife. The law has been applied to any project, federal, state or local, that involves federal funding, work performed by the federal government, or permits issued by a federal agency. The important objective of NEPA is to ensure that environmental factors are weighted equally when compare with other factors in the decision making process undertaken by government agencies. The effective mechanisms of NEPA are the requirement of federal agencies to prepare an environmental statement to accompany reports and recommendations for funding from Congress. This document is called an Environmental Impact Statement (EIS). The NEPA process consists of an evaluation of relevant environmental effects of a federal project or action undertaking. The NEPA process begins when an agency develops a proposal to address a need to take an action. Under NEPA there are three levels of analysis that a federal agency has to do in order to comply with the law. These three levels include: preparation of a Categorical Exclusion (CE)[241], preparation of an Environmental Assessment (EA) and Finding of No Significant Impact (FONSI); or preparation and drafting of an Environmental Impact Statement (EIS)[242].

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239 The purpose of an EA is to determine the significance of the environmental effects and to look at alternative means to achieve the agency's objectives. The EA is intended to be a concise document that (1) briefly provides sufficient evidence and analysis for determining whether to prepare an EIS; (2) aids an agency's compliance with NEPA when no environmental impact statement is necessary; and (3) facilitates preparation of an Environmental Impact Statement when one is necessary.

240 The NEPA's preamble is "To declare national policy which will encourage productive and enjoyable harmony between man and his environment; to promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man; to enrich the understanding of the ecological systems and natural resources important to the Nation...".

241 A CE is a category of actions that the agency has determined have a significant effect on the quality of the human environment . If a proposed action is included in the description provided for a listed CE established by the agency, the agency must check to make sure that no extraordinary circumstances include such matters as effects to endangered species, protected cultural sites, and wetlands exist that may cause the proposed action to have a significant effect in a particular situation.

242 The EIS is a more detailed evaluation of the environmental impacts when compared to the content of the environmental assessment. The crafting of EIS has many components including public, outside party and other federal agency input concerning the preparation of the EIS. These groups subsequently comment on the draft EIS. In some circumstance an agency may wish to undertake the construction of an EIS without the initial drafting of the environmental assessment. This will take place under circumstances in which the agency believes that the action will undoubtedly have adverse affects on the environment or is considered an environmentally controversial issue.

Since passage of NEPA, environmental impact assessment has become the key component of environmental planning and decision making in the United States, however, addition agency planners and decision makers have recognized a need for better understanding the social consequences of projects, programs and policies. In response to this need a group of social scientists formed the Inter-organizational Committee on Guidelines Principles for Social Impact Assessment (SIA), with the purpose of outlining a set of guidelines and principles that will assist agencies and private interest in fulfilling their obligations under NEPA, related authorities and agency mandates. By "social impacts" it means the consequences to human populations of any public or private actions-that alter the ways in which people live, work, play, relate to one another, organize to meet their needs and generally cope as members of society. The term also includes cultural impacts involving changes to the norms, values, and beliefs that guide and rationalize their cognition of themselves and their society. As it can be understood that a central requirement of NEPA is that before any agency of the federal government may take "actions significantly affecting the quality of the human environment" that agency must first prepare an Environmental Impact Statement (or EIS). Preparing an EIS requires the integrated use of the social sciences. The social science components of EIS's are called social or socioeconomic impact assessments, or simply SIA's. Several federal agencies have moved to develop SIA guidelines, but most have not. Even within agencies that have SIA guidelines there is variation on how the social component of NEPA is to be implemented. Since the passage of NEPA there has never been a systematic, inter-disciplinary statement from the social science community as to what should be in the content of an SIA.

Guidelines and Principles for Social Impact Assessment were first used when the Department of the Interior was preparing the EIS for the Trans-Alaska pipeline in the early 1970's. The purpose of it is to present the central principles and some operational guidelines for use by federal agencies in conducting social impact assessments. The guidelines and principles are the first systematic and interdisciplinary statement to offer guidelines and principles to assist government agencies and private sector interests in using SIA to make better decisions under NEPA and related authorities. These guidelines and standards are equally important for those communities and individuals likely to be affected by proposed actions in

order that they might conduct independent assessments or evaluate the adequacy of SIA's.

It should be noted that prior to the enactment of the NEPA, analysis of the social consequences of major projects often was fragmented and lacking in focus. For example, when construction related impacts of public works projects were at issue, attention was generally centered on economic considerations. The prevailing view was that money could compensate for any adverse impacts. There was minimal concern for social impacts even if entire neighborhoods had to be displaced so long as comparable housing could be located elsewhere. There was even less concern for the distribution or "equity" of these impacts on different populations. Also lost in this process was the important people attach to their communities and neighborhoods; and particularly to long-standing social networks that form the basis of support both for daily living and during periods of extreme stress and hardship. The passing of NEPA created a different, but somewhat vague, set of requirements for federal agencies; among these is the integrated use of the social sciences in assessing impacts on the human environment. Over the years, the legal definition of "human environment" has undergone substantial modification as a result of court decisions stemming from NEPA-related litigation.

In addition, Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act point-out that the "human environment" is to be "interpreted comprehensively" to include "the natural and physical environment and the relationship of people with that environment". Agencies need to assess not only so-called, "direct" effects, but also "aesthetic, historic, cultural, economic, social, or health" effects, "whether direct, indirect, or cumulative". The CEQ Regulations also contain another key provision that should be noted ". Economic or social effects are not intended by themselves to require preparation of an environmental impact statement". However, when an EIS is prepared "and economic or social and natural or physical environmental effects are interrelated, then the environmental impact statement will discuss all of these effects on the human environment". The EIS's are thus intended to provide a kind of full-disclosure procedure for federal decision-makers, who are then expected to consider the negative as well as the positive implications

6.2 What is Social Impact Assessment?

The Social Impact Assessment (SIA) was first formalized in the United States in 1969 when the Congress passed the US National Environmental Policy Act of 1969 (NEPA). The Act asked the federal and local government for an assurance of any federal activities, which might have a significant effect on the quality of the human environment, to have an assessment to be undertaken. SIA was first used during the discussion on the Trans-Alaska (Oil) Pipeline in 1973[243]. At the beginning, SIA faced with many problems due to the complexity and difficulty of the social issue including the criticisms about the standardization of approach, method of analysis and process, delivery of an unclear and in concise recommendation. However, in the 1990s, the method of the assessment has been improved and largely accepted by the modification of the approaches, process, methodology and technique in which it gives a more reliable recommendation than before.

It should be noted that the objective of SIA is to be able to help the decision maker to identify, estimate, address, assess and give a recommendation of the solutions to the problem of the actions or policies, and all reasonable alternatives to them, which will affect the quality of people's lives[244]. In other words, SIA can be seen as a checklist of things that they want to assess. According to the US National Environmental Policy Act of 1969, SIA does not require a policy maker to come up with a right or best decision, and it does not require projects to be stopped if they would be likely to create negative impacts. It merely requires that these impacts be publicly disclosed, and that the impacts and their potential mitigation be considered by policymakers before certain actions to be taken[245]. It should be understood that SIA is not a solution to the problems but it is a condition to the process of identifying and justifying the problem and solution of the problem of bio-prospecting.

Before defining what SIA is, it is necessary firstly to define what it is meant by "social impact". Social impact has been numerously defined, for example, "a significant or lasting change in people's lives brought about by a given action or

243 C.J. Barrow, Social Impact Assessment : An Introduction, 2000 p 9

244 National Oceanic and Atmospheric Administration, Guidance for Social Impact Assessment, May 1994

245 US Council on Environmental Quality 1978 Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act (40 CFR 1500-1508) Washington ,DC Us Council Environmental Quality.

actions"[246], "the consequences to human populations of any public or private actions that alter the ways in which people live, work, play, relate to one another, organize to meet their needs and generally cope as members of society. The term also includes cultural impacts involving changes to the norms, values and beliefs that guide and rationalize their cognition of themselves and their society"[247], or any policy or action that might change people's life. Therefore, according to the above definition, any activities that impact to the ways of human life both negatively and positively can consider to be called as a social impact.

The Social Impact Assessment has been defined as the *estimation* of how actions or policies, and all reasonable alternatives to them, will affect the quality of people's lives[248], the efforts to *assess or estimate*, in advance, the social consequences that are likely to follow from specific policy actions (including programs and the adoption of new policies), and specific government actions (including building, large projects and leasing large tracts of land for resources extraction)[249], *addresses* the impacts, both beneficial and adverse, of a proposed development that may affect the well-being, vitality and viability of an affected community that is the quality of life of a community as measured in terms of various socio-economic indicators, such as income distribution, employment levels and opportunities, health and welfare, education, and availability and standards of housing and accommodation, infrastructure, and services[250], *prediction and evaluation* of the social effects of a policy, program or project while it is in the planning stage-before the effects have occurred[251].

In the US, there are several cases referring to SIA. One of the leading cases can be seen from the case of *Northern Cheyenne Tribe v. Hodel* which involved a lease sale of the largest federal coal mill. In this case, the court voided the sale of the

246 C.J. Barrow, Social Impact Assessment : An Introduction, 2000 p 2

247 The Inter-organizational Committee on Guidelines and Principles for Social Impact Assessment, Guidelines and Principles for Social Impact Assessment, May 1994, p. 1

248 National Oceanic and Atmospheric Administration, Guidance for Social Impact Assessment, May 1994

249 The Inter-organizational Committee on Guidelines and Principles for Social Impact Assessment, Guidelines and Principles for Social Impact Assessment, May 1994, p. 1

250 Ad Hoc Open-ended Inter-seasonal working group on article 8(J) and related provisions of the Convention on Biological Diversity, Draft Guidelines for the conduct of cultural, environmental and social impact assessments regarding developments proposed to take place on, or which are likely to impact on, sacred sites and on lands and waters traditionally occupied or used by indigenous and local communities, 28 September 2004 (UNEP/CBD/WG8J/3/5)

251 Wolf, C.P.. Dowden, Huchinson, and Ross, Stroudsburg, Social Impact Assessment, (pa) (1974)

mill. One of the reasons was that the Environmental Impact Statement (EIS) from the Ministry of Interior did not discuss the implication of sale for social, cultural, or economic impacts on the Northern Cheyenne Tribe. The Judge James F. Batten gave his reason for overturning the EIS "for failing to turn its ostensible concern with socioeconomic impacts into any meaningful analysis of the extent of such impacts on certain groups of residents within the affected area, particularly the Northern Cheyenne Tribe"[252].

It should be noted that the main aim of SIA can be seen as a tool to identify and analyze the impacts of the proposed development, program or the policy. However, at the beginning, SIA only focused on the socio-economic impact in which it were strictly economic, rarely going beyond roads, sewer and water systems, and the other facilities and services making up what might be called the edifice complex. However, today, both "social" and socioeconomic" impact assessments essentially refer not just to sociology, economics, or any other single discipline but to interdisciplinary social science efforts in which the general consensus appears to be that non-economic and socio-cultural variables need to be examined as well as economic or demographic ones[253].

Therefore, it can be summarized that the objectives of SIA are as follows[254];

1. A systematic effort to identify, analyze and evaluate the social impacts of a proposed project.
2. A means for developing alternatives to the proposed course of action and of full range of consequences for each alternative.
3. A means of raising consciousness and the level of understanding of the implications of the proposals

In order to justify SIA, the academic literature has outlined SIA's approaches and process to identify the problem and how to find an alternative recommendation for the proposed project. The approaches and process can be briefly explained as follows:

252 Wolf, C.P.. Dowden, Huchinson, and Ross, Stroudsburg, n 185

253 William R. Freudenburg, Social Impact Assessment, Annual Review of Sociology, Vol. 12 (1986), p. 463

254 Burdge, R.J. and Robertson, R.A. (1990), Social Impact Assessment and the public involvement process, Environmental Impact Assessment Review 10(1), p 81-90

6.3 The approaches

The approach of SIA is a method of how the SIA is to be conducted. The approach of SIA has occasionally been changed in the last decades. There have been several approaches recommended by the sociologist, anthropologist, economist, political scientist such as technocratic approach, participatory approach, systems analysis approach, issues- or needs-centred approach, and etc. However, it is beyond the scope of this thesis to recommend which approach would be best for the problem of bio-prospecting because this issue should be left for the people concerned to decide. It can be understood that the approach can be changed over the period of time or places depend upon the perception of how the development should be liked. For instance, at the beginning of the twentieth century; the perception of SIA conducted did not include other stakeholders involved in the assessment because it was believed that the technocrat or academic would be the people who know best, however, this perception has been changed. The participatory approach has replaced the technocratic approach since it is to believe that the assessment for the society shall not belong only to technocrat but the approach to assess the project must also involve with the people who has the potential to be effected and they must also be part of the decision making process. It should also be noted here that the approach of conducting the SIA should also take socio-economic differences of the country into consideration. For instance, in the business world, when the company wants to invest on anything, they tend to look at how much profit can they generate or so called "minimize cost-maximize profit", however, it might be different on the activities or the policies for the public sector because in the public sector, sometimes, it is necessary for the government to consider the welfare of the people more than the profit of the project or the policy as it can be seen in the subsidy policy in the agriculture sector or in the aviation industry in many countries.

In recent years, the SIA approaches have been developed as a result of a social and economic change. One of those approaches, as mentioned, is the public involvement approach[255]. The importance of public involvement approach is to be able use the local knowledge and their information and understanding that has been

255 Public involvement has been defined as a process for involving the public in the decision making process of an organization. Richard Roberts, Involving the public: The international handbook of social impact assessment 2003 p. 259

acquired by the community in corroboration with the experts, academic, bureaucrats as an information in formulating and evaluating SIA processes. In many developing nations, the decision about and the use of benefit sharing arising out of the community's natural resources might come from the central government in which it might not really reflect to the desirability and interest of the community, therefore, using the public involvement approach in every part of SIA process to identify the problem can ensure that the need and interest of the community in particular the indigenous people will be assured. In addition, the experience of involving in the issue through the public involvement approach can be shared with the other communities when the other communities have to deal with the benefit sharing issue for their natural resources. SIA can also encompass the empowerment of local people; enhancement of the position of women, minority groups and other disadvantaged members of society; development of capacity building; alleviation of all forms of dependency; increase in equity; and a focus on poverty reduction[256]. The use of a public involvement approach will also ensure that the core values of SIA were identified.

Nowadays, there are two models of public involvement those have been using which are the consultative model and participatory model. For the consultative model, it refers when the public an stakeholders may be consulted at various points throughout a public process but are not involved directly in developing the material or assessing the effects whereas the participatory model offers the public or the stakeholders an opportunity to participate more directly in decision making, building a feeling of ownership among participant which can provide a mitigating influence[257]. However, it is beyond the scope of this paper to explain which model is better than the another, nevertheless, it should be noted that the World bank is one example of an organization that is attempting to move towards from consultative model to participatory model. Nonetheless, the key point that this paper would like to address with regards to public involvement is that either consultative or participatory models, they do offer an interactive and involvement that the public or the stakeholders will be informed and able to give their opinion in the different stages of SIA process.

256 Frank Vanclay; Conceptual and methodological advances in social impact assessment: The international handbook of social impact assessment 2003 p. 3

257 Frank Vanclay, n 256, p. 260

Because of this, SIA report with the public involvement will truly reflect the needs of the affected people and stakeholders.

It seems to be that the use of SIA approach shall be left depend upon the project, situation, geography, and academic and shall take into an account or integrate with different areas of subjects in the assessment including sociology, anthropology, social psychology, economic, environment, and etc in order to understand the project more socially sounded. It is to believe that there shall be no universal approach for any kind of any project in which each country shall either develop its own approach of SIA because each country has socioeconomic and cultural differences, however, the international institution such as the World Bank, the COP of the CBD can develop the non-binding standardized approach in which it can guide the member of WTO a general idea of how the approach should look alike similarly to the Bonn Guideline.

6.4 The Process

The objective of the process is to be able to enhance the effectiveness of SIA. If the process of the SIA is ineffective, the manipulation of the outcome of SIA can be jeopardized. There are at least eight steps of SIA process have been recommended[258] which are Scoping/ problem identification, Profiling, Projection, Assessment, Evaluation, Formulation of alternatives, Mitigation, and Ongoing monitoring[259]. However, it should be noted that the process of SIA can be added or reduced as seen appropriated. There shall be no universally-binding accepted process as long as it is able to serve the objective of the process of SIA. The example of how the SIA can be used through the process of SIA could be seen in the later section in order to address the problem of bio-prospecting. In order to strengthen the process of SIA, the framework can also be helpful. The framework will help us to understand how SIA process can be reasonable. It is called the conceptual framework. The conceptual

258 C.J. Barrow, Social Impact Assessment : An Introduction, 2000 p. 37

259 1. Scoping/ problem identification: Identifying the potentially impacted people and their concerns in an attempt to determine the type, scale and focus of assessment. 2. Profiling: Determination of what is likely to be impacted and identifying the indicators to measure 3. Projection: Making projections of what is likely to happen and who is affected 4. Assessment: Determining the magnitude and effect of the impacts 5. Evaluation: An analysis of trade-offs, what are the net benefits and whether the overall impacts is acceptable. 6. Formulation of alternatives: Develop reasonable alternatives to the proposal
Mitigation: Measuring to counter unwanted impacts are identified 7. Ongoing monitoring: Lesson learned and feedback of the actual impacts compare with the projected impacts

framework provides a way of thinking for a SIA conductor to understand and to be able to identify the first three of the eight steps of SIA process[260]. The conceptual framework has been designed as a tool to provide insight into the relationship between demand side and supply side.

6.5 The linkages between SIA and the problem of bio-prospecting

With regards to the research question of how Thailand can legally deal with the problem of bio-prospecting, there are several justifications of why SIA can be used as a tool to address the problem of bio-prospecting as can be seen as follows:

6.5.1 The impact of bio-prospecting on society

It can be seen that the bio-prospecting activities does have a lot of both positive and negative impacts to the people concerned. The positive impacts can be seen from the improvement of products or the process from biotechnology such as the increase of yields in the field, the reduction of the use of pesticide, the recognition of innovator's right, the guarantee of the investment, and etc. However, it is also undeniable that it also raises some negative impact and unresolved issues as well. The negative impacts can be seen between patent law and the problem of bio-prospecting such as the bio-piracy issue, the implication of bio-prospecting under the patent law to the society both in terms of the higher price of the commodities which impact to the income of the farmer, the dependency of the people concerned on the biotechnology, the criteria of patentability on biotechnology in which it does not recognize the socio-economic differences other than the innovator/ investor's interest, the sovereign rights issue, the benefit sharing issue[261].

Looking from the above problems, it can be said that the bio-prospecting does have affects to various stakeholders. Those problems are based on many factors

260 The first three are scoping/ problem identification, profiling, and projection.

261 There are several questions arisen about the patent law on biotechnology with regards to the bio-prospecting problem. Those questions are, for example, the implication of patent law on biotechnology to various stakeholders, the problem between patent law and bio-prospecting, the problem between biotechnology and agriculture sector, and etc.

including the differences of socio-economic conditions, legal enforcement, and etc. It is to be understood that one of the problems arising out of the utilization of commercial exploitation of bio-prospecting is the rapid change of technology with the slow process of the political decision in particular at the international level in order to keep up with the surrounding issues[262]. It can be seen in many cases that the problem of bio-prospecting under patent law does have impacts to the society as can be seen, for example, in the Indian Basmati case, the turmeric case, the Thai fragrant case, the Mali case. As a consequence, there have been many criticisms from the developing nations that if the patent law remains to be interpreted as it has been and the criteria of patentability still limit to novelty, inventive step and industrial application, then the problem arising out of the patent law will never be solved. It should be noted that the SIA is an important safeguard tool to ensure that the grant of bio-prospecting or patent protection will not cause any harm to the other people as can be seen in many discussion for years and the disputes arising out of the patent protection for the problem of bio-prospecting such as in Basmati Case, the Thai Jasmine rice as it could be seen as a good indicator that the bio-prospecting activities and patent law does not provide any mechanism to keep itself up to the change of time and technology. In addition to that, at the international level such as at the WTO, there have been numerous attempted to review and amend the TRIPs agreement in order to address the issue/s faced by the member of the WTO in numerous ministerial meeting and general councils but they have not been successful due to largely political reasons.

6.5.2 The implications of using SIA for the problem of bio-prospecting

SIA can be used as a tool to identify and be part of the problem-solving solutions for various stakeholders to address and identify the cost and benefits on several issues surrounded in particular the problem of bio-prospecting. SIA can be developed as another condition in an easy manner and economically justified in order to address the problem of bio-prospecting. There are three options in which this thesis is of the opinion of how SIA could be used to address the problem of bio-prospecting. The first option is to put it as additional criteria of patentability. The

262 WTO‘s decision must be a consensus

second option is to put it as a tool to rational the grant of access and use of biological resources. Third option is to put it as a tool under the benefit sharing scheme in order to justify the benefit arising out of the utilization of biological resources.

6.5.2.1. The first option: making SIA as an additional criteria of patentability

This option can directly address the problem of bio-prospecting because it can be one of safeguard mechanisms to ensure that the patent office will look at the consequence of grant the patent protection in the term of social impact not only from the legal point of view. SIA can be used as an important condition to deal with the problem of bio-prospecting under the patent law in order to recognize the sovereignty of the country to determine the appropriateness and difference of social and economic conditions before the patent office grant the patent protection. In addition, the TRIPs agreement has clearly stated in the article 8 to allow the member to adopt measures, formulating or amending their laws and regulations, to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development[263]. However, in the articles of TRIPs, there is no mechanism that can ensure and adopted any measures to promote the public interest. The patent office shall not only have the role of determining whether the product/ process have passed the criteria of patentability and exceptions to patentability because it would be unwise, rigid, and danger to the society in sprit of the fact that the development of technology, issues, and socio-economic conditions goes faster than political decision both at the domestic and at the international level. Even though, many academic might point out that the court can still interpret the law in favour of the change of time and technology, in spite of that, it might be only suitable for the case law country.

In addition, the Bonn Guidelines also suggested that a country shall establish a competent authority to be responsible for advising on the issues. Therefore, the patent office can use the guideline as an example to establish its own division comprising of experts and stakeholders to examine and to justify the product/ process on the issue of

263 TRIPs/ Art 8

bio-prospecting, about *whether and how* the product/ process would maximize the public interest through the use of SIA.

However, it should be noted that to put SIA as a criteria of patentability will be a politically difficult option to do so since as mentioned, TRIPs amendment must come in a form of consensus and some member of WTO might see it as a technical barrier to trade but it depends on how the member of WTO justifies and present SIA to the other member of the WTO.

6.5.2.2 The second option: making SIA a condition when evaluating the grant of access and use of biological resources

SIA can be used as a tool in assessing the grant of use and access of biological resources (PIC). The second option will use SIA as a tool to assess whether the grant of access and utilization of biological resources is sound and feasible. SIA will be used to help the decision maker to determine the purpose and objective of access and utilization and to understand the cost-benefit of granting an access and use of biological resources in her countries in which the resources might be used for the product/ process.

For the use of SIA for assessing the grant of use and access of biological resources, it can be further explained that according to Bonn Guideline, the guideline has recommended the contracting parties to provide parties and stakeholders with a transparent framework to facilitate access to genetic resources and ensure fair and equitable sharing of benefits[264]. The Bonn guidelines have recommended that the Prior Informed Consent (PIC) could be used to recognized sovereign rights of the country and deal with the problem of bio-prospecting for the product/ process. By doing so, the Guideline has recommended the guideline in the development process of access and benefit sharing scheme as follows:

For the PIC, the guideline has recommended the contracting parties of the CBD *to establish competent authority to grant and to provide the evidence of PIC*. By doing so, the guideline has recommended several processes including that the contracting parties is *to establish a mechanism for consultation of relevant*

264 Bonn Guideline/ Annexes 1 E: 11B

stakeholders[265]. The guideline emphasizes the importance and involvement of the indigenous and local community[266].

Therefore, this thesis see that, according to the above explanations, SIA can be a justified tool to ensure that the decision making process of the PIC as recommended in the second option in which it will encompass the needs of the relevant stakeholders and provide a complete picture of the effect of the bio-prospected product/ process as also recommended by the guideline will bring the maximized profit to the society. Because of this, the role of SIA could contribute and strengthen PIC.

By putting SIA as a tool to assess the PIC, it will address the problem of bio-prospecting and uphold the sovereignty of state over natural resources. It should be noted here that many people might think that the use of SIA in the first and second option will be a mean to prevent the authority to grant a monopoly rights over the product/ process or not allowing the biological resources to be taken out of the country respectively. However, this can be explained that, first, SIA is a tool to determine whether such action is sound and benefit the owner of the biological resources. Secondly, it would be unwise for any country to jeopardize SIA process in order to prevent the biological resources being bio-prospected because the country that uses SIA will bear the burden of prove and her reputation and credibility when it goes to domestic and international court. The country who appeals to the court still has her right to investigate the SIA processes as happen in many cases at the WTO panels and the result of jeopardizing SIA will result to the trade concession and compensation.

6.5.2.3 The third option: making SIA a means to assess benefit sharing schemes in separate legislation

It is argued here that SIA can be used to assess whether benefit sharing to be made is appropriate and comes up with the best decision for cost and benefit analysis arising out of the utilization of biological resources. SIA can be used as the

265 Bonn Guideline/ Annexes 4 C: 27 E

266 Respecting established legal rights of indigenous and local communities associated with the genetic resources being accessed or where traditional knowledge associated with these genetic resources is being accessed, the prior informed consent of indigenous and local communities and the approval and involvement of the holders of traditional knowledge, innovations and practices should be obtained, in accordance with their traditional practices, national access policies and subject to domestic laws.

information to determine whether the offer is justifiably reasonable because SIA will help the policy maker to identify all the cost and benefit that may arise. Therefore, it could be seen that SIA process can be used to help the assessor to determine and justify the BS scheme agreement.

It should understand that the economic benefit arising out of the bio-prospecting is a major reason why the bio-prospecting has become an issue in the international forum. Even though the Bonn Guidelines has outlined the basic requirements and indicative list of mutually agreed terms under the benefit sharing scheme, but it cannot be guaranteed that the mutually agreed terms in the Bonn Guidelines will be an outcome that reflect the needs of the stakeholders especially when the BS scheme under the Bonn Guidelines is a voluntary scheme. This is why the role of SIA could strengthen and justify the decision of the competent authority for the product or process and also on the benefit sharing scheme. There are several reasons why the Bonn Guidelines is still considered as an ineffective mechanism for the country who own the natural resources. First, the purpose of the Bonn Guidelines has been recommended as a voluntary scheme which does not need to be abided by the patent applicant and therefore, it would not thoroughly deal with the patent law with regards to the problem of bio-prospecting. Second, because of the above reason, the country who owns the natural resource will be left no choice but to accept the term offered by the innovator. (The examples can be seen from my previous chapter: the Mali case study[267]). Third, the main concern of the Bonn Guidelines is an economic return rather than the adverse impacts to society from the utilization of natural resources. The adverse impacts have not been given an importance in the Bonn Guidelines. Forth, under the Bonn guidelines can be understood that the benefit sharing will only come into existence when the product or the process obtains a benefit as a result of a commercial exploitation. Therefore, if there is no benefit or profit from the product, then there will be no benefit sharing to the country who owns the natural resource. It seems to be that the benefit sharing is something that voluntarily transferred by the innovator to another, not as a mutually agreed term as mentioned in the Bonn Guidelines. Fifth, the Bonn guidelines do not provide any effective mechanism to evaluate and justify the decision of the benefit sharing result.

267 World Intellectual Property Organization, The Role of Intellectual Property Rights in the Sharing of Benefits arising from the use of Biological Resources and Associated Traditional Knowledge: Selected Case Studies

Therefore, in order to solve the problem of bio-prospecting, it is necessary to ensure that benefit sharing is a binding obligation and in the benefit sharing scheme, it must come up with a condition that can be identifiable, quantifiable and measurable which recognize the determination of the country who own the natural resource and commit to sustainability and scientific integrity and uphold an ethic that advocates openness and accountability, fairness, and equity and defends their rights. Therefore, this thesis also sees the importance of introducing SIA as part of a condition under the benefit sharing scheme for the purpose of evaluating the justification and the procedure of the scheme and to ensure that, before the agreement is to be reached, all aspects would be assessed justifiably and orderly in order to secure that the economic and social benefits from the benefit sharing scheme are really rewarded back to and serve the need of the community.

In the conclusion, there are two problems why the benefit sharing scheme has not effectively dealt with the problem of bio-prospecting. Those are, first, it is not a binding instrument and second, the benefit scheme does not provide any condition to explain the reason of why the benefit sharing decision (when it is already gone to the negotiation process) is justified. For the second reason, SIA is recommended in this chapter as an important tool to maximize the benefit and abide the rights of the natural resources' owner under the BS scheme. In addition, SIA can also be used as a tool to identify the problems arising out of the use of natural resources such as the social problems; as a consequence, the policy maker can use the information to decide about the cost and benefit arising out of the utilization of natural resources.

SIA will ensure that the local people or the country can see whether the product/ process or the offer will really reflect to the need of the country or the community both economically and socially. In order to make SIA justify, the academic has outlined SIA's approaches and process to identify the problem and how to find an alternative recommendation for the proposed project. The role of SIA can, sometimes, go far beyond the prediction of adverse impacts and determination of who wins and who loses. The reason why SIA is considers being an important tool because SIA provides justifications and reasons in every step of its approaches and processes in determining the problems.

6.6 How can SIA be put into practice with regards to the problem of bio-prospecting?

As previously mentioned, there are eight steps in the process of SIA in order to get the answer, and illustrations of how SIA could be put into practice will be given in the following paragraphs. It should be noted that the following paragraphs will only explain five steps of SIA process because eight steps are theoretically written by academics but when it comes as a tool for the problem of bio-prospecting; this thesis has modified and applied the theoretical steps to practical steps of five. This will give an idea of how it would work out with regards to the problem of bio-prospecting.

6.6.1. Scoping/ problem identification: In this part, the reason of conducting this part is to examine the implication of bio-prospecting. In this part, it will give an assessor to be able to identify the problems of granting a patent on product/ process or of the grant of access and utilization of the biological resources or to weighing the benefit under the BS agreement that likely to happen to the stakeholders. In order to be able to identify, the assessor must be able to understand a complete picture of such action including the legal obligations under the relevant international agreement such as the TRIPs, CBD, ITPGR, the social effects result of the product/ process from the patent monopoly, and etc. This part can be strengthening with the public participation as recommended by the Bonn Guidelines when the product/ process relate to a relevant stakeholder.

6.6.2. Profiling: In this part, it will determine the likelihoods of what is to be impacted and identify the indicators to measure. This part will enlarge the picture of the first process. The profiling process will be able to list all the impacts those likely to happen from such action. In order to do so, it will also indicate the list of sources for the purpose of justifying the profiling process. The sources of information include data from a project proponent, records of previous experience with similar actions, census and vital statistics, documents and secondary sources, field research including interviews, hearing, group meeting, and surveys.

6.6.3. Projection: In this part, the projection process will make a projection of what is likely to happen and who will be affected from the grant of patent with regards to bio-prospecting or permit the utilization of the resources or would it be economically and socially viable for benefit sharing decision. In order to make a

good projection, the assessment and evaluation processes will be able to help the assessor to understand the projection because the assessment process will determine the magnitude and effect of the impacts and the evaluation will analysis the trade-offs, what are the net benefits, and whether the overall impacts is acceptable.

6.6.4. Formulation of alternatives: In this part, the decision maker can use all the above information to determine whether the grant should be made or how much benefit sharing shall be shared in order to address and alleviate the issues/ problems. In order to determine the how much, how, and when the sharing should be made should be left for the expert and relevant stakeholder to determine.

6.6.5. Ongoing monitoring: This process will be used for a lesson learned and feedback of the actual impacts compare with the projected impacts. The monitoring process can be used as a tool to justify the amendment of the BS agreement when it is needed

Therefore, SIA can be seen as a justified tool because of its transparent and a systematic way of administering the problem and solution of the problem. In addition, if SIA has been included as an additional criteria of patentability or the condition of granting an access or use of biological resources or to justify the BS scheme, then, SIA would enhance the concept of sovereign rights of the country in a sense that the country can impose extra conditions for the problem of bio-prospecting in various problems in which it will reflect the need and differences of the socio-economic conditions when, presently, TRIPs could not[268]. SIA can also be seen as a democratic process to deal with the issues and still withstand the obligation of the TRIPs agreement in particular article 7 and 8. Because of these, SIA shall be considered as a tool to assess or to identify the problem, recommending the alternatives and most importantly providing information for the decision maker to see whether such proposed product/ process is suitable for the community or for the country. It is a tool that can quantitatively and qualitatively rationalize before the patent protection can be given. This point is very important because the assessment would be the best indicator to quantify the benefit arising out of the patentability of the biological product or process in which it would suggest the suitability of the patent law in a place where it wants to be patented.

268 It could be done at the formulation of alternatives in which it is one of the eight step of SIA process

6.7 Conclusion

The Social Impact Assessment is a new method to qualitatively and quantitatively help the decision making process. SIA will help the decision maker to identify the benefit and cost when permitting the bio-prospecting activities and when the benefit sharing scheme is to be made. This chapter has given three options for the policy maker to choose which are, first, to put it as additional criteria of patentability, second, to put it as a tool of granting an access or use of biological resources, and third to use SIA as a justifier the BS scheme. However, it seems to be that the second and the third options are likely to be chosen in order to address the problem of bio-prospecting because the first option will face with the political difficulties which may prevent the first option being used in practice.

The next chapter reviews the use of biodiversity laws as a potential way of dealing with the problem of bio-prospecting without contravening with the TRIPs agreement. It will give an overview of how biodiversity legislation has been written in different countries and regions in order to understand the strengths and weaknesses in different laws and draw lessons on how biodiversity legislation might be best used in Thailand.

Chapter 7:
The Review of the Biodiversity laws and Plant Varieties Protection Acts

Potential conditions for dealing with bio-prospecting were explored and analysed in the previous chapter. The next question arose of how these conditions could be used or implemented in which two options were identified. The first option would be that States introduced them as additional criteria of patentability that the inventor has to meet before applying for the patent protection. The second option would be that those conditions could be introduced in legislation which would be implemented independently from patent law. This legislation will be called the Biodiversity legislation. The enactment of the Biodiversity legislation will reaffirm and recognize their sovereign rights over the natural resources through the use of PIC and the benefit arising out of the utilization of biological resources though the benefit sharing scheme both assisted by the SIA.

The purpose of this chapter is to examine and give comparisons of different types of legislation related to biological resources from around the world in order to find the common grounds and differences in order to see how it would be best for this thesis to apply to the Biodiversity laws in Thailand for the problem of bio-prospecting. Those laws cover patent law, plant variety protection (PVP), and biodiversity protection.

This chapter will be divided into two sections. The first section will analyze legislation with regards to the Intellectual Property protection: patent law and the plant variety protection law. The second section will be analyzing legislation with regards to the control of and access to biological resources such as the Biodiversity laws.

7.1 Legislation with regards to the Intellectual Property Protection: patent law and the plant variety protection law

The reason why this chapter examines PVP and patent law is to discover whether the PVP law or patent law of any country could be seen as a good example

that can deal with the problem of bio-prospecting. For PVP legislation, there are two models of protecting the plant varieties: either through the UPOV models[269] or the *Sui generic*[270] system in which the country can choose to design its own criteria of granting new plant varieties protection. With regards to the problem of bio-prospecting, it seems to be that the UPOV models do not provide any mechanism to deal with the problem of bio-prospecting[271]. Therefore, many countries those aware of the importance of their natural resources tend to go for the second option which chooses to design or develop their own model of new plant varieties protection. It shall be noted that the requirement to receive a new plant variety protection still similar to the UPOV model[272] however, the country where chooses the *sui-generis* may require an applicant to disclose additional information with regards to the new plant varieties before granting the protection as an additional requirement for the process of requesting a new plant variety protection. This thesis will illustrate that there are countries have chosen the *Sui generic* system in order to equip with conditions that can deal with the problem of bio-prospecting.

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269 The International Union for the Protection of New Varieties of Plants, known as "UPOV" has the main mission to provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society. UPOV has been established by the International Convention for the Protection of New Varieties of Plants (the "UPOV Convention"), which was signed in Paris in 1961. The Convention entered into force in 1968. It was revised in Geneva in 1972, 1978 and 1991. The main activities of UPOV are concerned with promoting international harmonization and cooperation, mainly between its members, and with assisting countries and certain organizations in the introduction of the UPOV system of plant variety protection.

270 Sui generis is a Latin expression, literally meaning of its own kind/genus or unique in its characteristics. The expression was effectively created by scholastic philosophy to indicate an idea, an entity or a reality that cannot be included in a wider concept.

271 For the conditions for the grant of breeder's right, the UPOV 78 and 91 is the same conditions which are the new, distinct, uniform and stable. However, the main differences between UPOV 78 and 91 are about plant breeder's right. UOPV 78 does allow the farmer to save and exchange the protected varieties among farmers or develop a new line of plant variety without asking for permission and paying loyalties. However, the UPOV 91 gives tougher protection which is the UPOV 91 give the permission to the member countries to allow "may" to farmer to save to keep seeds and other propagation material from protected varieties for use on their own farms which is different from the UPOV 78 as an automatic right. In addition, breeders face new restrictions in the free use of genetic material, since the holder of a variety may now limit the right of another breeder to develop, produce, sell, stock or simply use any variety which is "essentially derived" from a previously protected variety. Lastly, the protection under the UPOV 91 has extended the breeder's right to the import and export of protected varieties, and to control of the harvest produced from those varieties without breeder authorisation whereas the UPOV 78's breeder rights only extends to the production for the purposed of commercial marketing, offering for sale, and the marketing.

272 Based upon the UPOV model, the new plant varieties can receive a new plant varieties protection when it meets the criteria in this case would be the novel, distinct, uniformity, stability, and the denomination.

For the PVP law, this chapter has examined 22 PVP laws. In the 22 PVP laws, there are 17 PVPs laws[273] those are the same as the UPOV model which does not address any mechanisms for the problem of bio-prospecting. For instance, the PVP Act of Chile does not require any document that addresses the problem of bio-prospecting neither the criterion of the protection[274] nor in the other formalities[275]. Similar to the Korean Seed Industry Law, the requirement to receive the seed protection are New, distinct, uniform, and stable[276] and the application for a new plant variety protection does not require any prior informed consent[277] which is similar to the Republic of Panama's PVP for the grant of plant varieties protection[278] and the application for plant variety protection[279].

However, the other 5 PVP laws have addressed conditions for the protection of the problem of bio-prospecting. Those legislations are New Plant Varieties Act of Malaysia 2004, New Plant Varieties Act of India 2001, Law on the Protection of Intellectual Property Rights of Egypt, New Plant Varieties Act of Pakistan, and New Plant Varieties Act of Bangladesh.

This chapter will examine the 5 PVPs law that have addressed the conditions for the protection of the problem of bio-prospecting. The details of the legislations can be seen as follows:

7.1.1 The New Plant Varieties Act of Malaysia 2004

In the PVP of Malaysia, the Act gives the function and power to the Plant Varieties Board to consider and approve or reject applications for registration of new

273 New Plant Varieties law of Paraguay 2000, New Plant Varieties Act of the Republic of Trinidad and Tobago 1997, Plant Varieties Act of Argentina, New Plant Varieties Act of Belize, New Plant Varieties Act of Panama, Draft New Plant Varieties Act of Srilanka, New Plant Varieties Act of Zimbabwe, Iraq Patent Law and new plant variety protection, Jordan Plant Variety Protection Act, Hong Kong Plant Varieties Protection, New Plant Varieties Regulations of China, New Plant Varieties Act of Chile, Korea Seed Industry Law, New Plant Varieties law of the Republic of Panama, Plant Breeders' Rights Act of 1976, Bolivia Regulations on Protection of Plant Varieties, New Plant Varieties Act of Kenya 1972 and New Plant Varieties Regulations of Kenya 1994

274 Chilli PV / Art 8

275 Chilli PV / Art 20

276 Korean Seed Industry Law/ Art 10

277 Korean Seed Industry Law/ Art 26

278 Panama's PVP/ Art 243-247

279 Panama's PVP/ Art 256

plant varieties and grant of breeder's rights. However, the Act has addressed the problem of bio-prospecting through the PIC mechanism by requiring the applicant to contain information relating to the source of the genetic material and a prior written consent of the authority representing the local community or the indigenous people in cases where the plant variety is developed from traditional varieties or supported by documents relating to the compliance of any law regulating access to genetic or biological resources[280]. For the benefit sharing scheme, even though the PVP of Malaysia has not stipulated about the benefit sharing scheme, nonetheless, it can be understood that any benefit sharing scheme can be developed if the new plant variety come from traditional plant varieties because the plant breeder needs to receive the PIC from the local authority. In the other words, it can be said that the BS scheme will be dealt privately between the community and the applicant before the written prior informed consent is given. However, this thesis find that the PVP of Malaysia should have the section that mention about the benefit sharing scheme because the BS scheme and its regulations can be seen as a legal tool and protection for the community to use it as the formal requirement when they negotiate the benefit sharing agreement. This can be explained and seen in many countries which have specified what shall be the details in the benefit sharing agreement[281]. In addition, Article 23 of Malaysia Act also provides the other important mechanism for the bio-prospecting problem by levying several grounds for the opposition to application for registration of a new plant variety and grant of breeder's right in particular article 23(1) (b) and 23(1) (c)282. In order to use article 23(1)(c), the opponent must show the court how

280 Article 12 is An application for the registration of a new plant variety and a grant of a breeder's rights shall be made to the Board in the prescribed manner and shall (e) contain information relating to the source of the genetic material or the immediate parental lines of the plant variety and (f) be accompanied with the prior written consent of the authority representing the local community or the indigenous people in cases where the plant variety is developed from traditional varieties and (g) be supported by documents relating to the compliance of any law regulating access to genetic or biological resources

281 This can be seen, for example, the Ministry of Environment and Forest Notification of India

282 Article 23. (1) Any interested person may, within three months from the date of publication of an application for the registration of a new plant variety and grant of a breeder's right, give notice to the Board and the applicant of his intention to oppose the application on any or any combination of the following grounds: (a) that the person opposing the application is entitled to the breeder's right as against the applicant; (b) that the application for the registration of the new plant variety and grant of a breeder's right does not comply with the requirements of this Act; (c) that the application for the registration of the new plant variety and grant of a breeder's right is contrary to public order or morality; (d) that the application for the registration of the new plant variety and grant of a breeder's right may produce a negative impact on the environment.

(2) The notice shall be in writing in the manner to be specified by the Board in writing and shall include a statement of the grounds of opposition.

the new plant varieties which receive an intellectual property protection would contrary to the *ordre public* in order to revoke the grant. Therefore, if the local community feels that the bio-prospector has done anything that immoral or *ordre public* then the local community may ask the board to revoke the application. This may be the other way to deal with the problem of bio-prospecting.

7.1.2 The PVP Act of India, 2001

For the problem of bio-prospecting, the PVP of India requires the applicant to disclose the information before receiving the new plant variety protection. This can be seen in the article 18: form of application of this legislation in particular section (e) and (h)[283] which require the applicant to complete information of the parental lines from the variety that has been derived and written prior informed consent. Even though the PVP Act of India does not mention in detail about the written prior consent and the benefit sharing scheme in the PVP legislation but it can be understood that the lawmaker has already got another legislation that directly deal in details with the problem of bio-prospecting in which the details of PIC and BS scheme have been written. That legislation is called the Biodiversity Act of India 2002 as it will be later examined.

7.1.3 Draft New Plant Varieties Act of Bangladesh

This Draft legislation was introduced by the National Committee on Plant Genetic Resources (NCPGR) in 1998 in conjunction with the Biodiversity and Community Knowledge Protection Act of Bangladesh. In this Draft, the NCPGR had written the PVP with two major objectives. The first objective is to grant the intellectual property protection to the new plant varieties. The second objective is to protect the community which owns the intellectually innovation and biological resources which has addressed in details of how the law should be written in order to

283 Form of application (e): contain a complete passport date of the parental lines from which the variety has been derived along with the geographical location in India from where the genetic material has been taken and all such information relating to the contribution, if any, of any farmer, village community, institution or organization in breeding, evolution, or developing the variety; (h) contain a declaration that the genetic material or parental material acquired from the breeding, evolving, or developing the variety has been lawfully acquired; and 9I) be accompanied by such other particulars as may be prescribed

address the bio-prospecting problem. This can be seen, for example, that at the beginning of this draft, it has started with the rights of the community[284] in which the act indicate that the main objective of the draft is to retain the ownership of the plant varieties held as a common property. In addition, in the Article 7: general provision, the draft had stipulated that the innovation such as new plant varieties shall only be acknowledged through and by the community and any new varieties that have been proven to have a negative consequences, on the biodiversity and/or the existing biological and genetic resources and the related intellectual and cultural knowledge and practice, including genetic and cultural erosion, will not be protected under this Act[285]. The key mechanisms of the draft with regards to the problem of bio-prospecting go to the article 10 and 11. The article 10: Rejection of applications, it had stipulated several grounds where the application shall be rejected such as the non-disclose of vital information, invalid contract of benefit sharing agreement, against the objective of the Biodiversity and Community Knowledge Protection Act[286]. In addition, the article 11: incomplete application had instructed the competent authority to consider application is incomplete. The incomplete information include the financial terms of the benefit sharing between the applicant and the community, the details of benefit sharing contracts such as terms of technology transfer, sharing of scientific and technical knowledge, the insufficient information about materials, intellectual and cultural knowledge[287]. For the benefit sharing scheme, even thought

284 Draft New Plant Varieties of Bangladesh / Art 3: Scope

285 Draft New Plant Varieties of Bangladesh / Art 7.6

286 Applications shall be rejected on grounds of: 1. Non-disclosure of vital information: If any applicant(s) used the following in the innovation but did not disclose the information in the application. (a) Community Varieties, local or indigenous varieties and/or wild species or any part of the plant varieties or any biological and genetic materials and related intellectual and cultural knowledge from Bangladesh or from countries that are Party to the Convention on Biological Diversity; (b) Advantage from the local and indigenous knowledge of the present or the past of a Community. 2. Non-indication of origin: If applicants who fail to provide the origin of biological and genetic resources and related intellectual and cultural practices used in the innovation. 3. Invalid contract of benefit sharing: If the biological or genetic resources and related intellectual and cultural knowledge of any Community/ies was used and/or any Community was involved in the innovation, but (a) No fair and equal benefit sharing contract has been signed between the innovator and the Community/ies (b) Terms of contract are detrimental to the national interest or against the interest of a Community holding Residual Titles, and (c) If National Biodiversity Authority does not accept the nature and content of benefit sharing contract because it is against the spirit and content of this Act as well as against Biodiversity and Community Knowledge Protection Act of Bangladesh

287 (a) The financial terms of the benefit sharing contract of the applicant(s) with Community/ies from the commercial and technological gains of the New Plant Variety, applied for protection, is insufficient. The National Biodiversity Authority may assess the gains from the commercial profit potential of the New Plant Variety. b) The benefit sharing contract by the applicant, in terms of technology transfer, sharing of scientific and technical knowledge, research communication, skill sharing and in other

the draft did not specify exact amount of the benefit sharing that might go to the community but it seems to be that the requirement to disclose the benefit sharing agreement which also need to receive approval from the National Biodiversity Authority shall be seen a filter on the appropriateness of the level of benefit arising out of commercialization.

7.1.4 Law on the Protection of Intellectual Property Rights of Egypt

For this legislation, the law treats patent law and PVP rights separately. Therefore, this chapter would like to divide the Law on the Protection of Intellectual Property Rights of Egypt into two parts which are the PVP part and the patent law part.

For the PVP part, in the book IV: Plant Varieties, the Article 199 and 200 of this legislation was written to protect the use of biological resources for the protection of new plant varieties in Egypt which provide both a direct and indirect legal clause for the problem of bio-prospecting as can be seen as follows:

Article 199, in particular 199(2), indicates that if the new plant varieties are to be harmful to the natural environment, biological diversity, economic and has social effect, and incompatible with the values and beliefs of the community[288], then such protection shall not be granted. However, the law has not defined how the economic and social effects can be determined or evaluated or how the values and beliefs of the community can be assessed. The law has not provided any mechanism that can be

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relevant areas, with the Community/ies is insufficient and inadequate. (c) The benefit sharing contract between the applicant(s) and Community/ies is not fair and does not reflect the spirit and objective of the Biodiversity and Community Knowledge Protection Act of Bangladesh. (d) the information provided is inadequate, incomplete or mistaken about materials and intellectual and cultural knowledge, particularly about the origin, that were used in the innovation, or about the Community/ies involved in the innovation.

288 Law on the Protection of the Intellectual Property Rights of Egypt/ Ar 199: The Minister of Agriculture may, on the recommendation of the Ministerial Committee referred to in the Article 19, limit the exercise of the breeder of all or some of his rights provided for in this law in any manner with the aim of safeguarding the public interest, and in particular if it appears that the protected plant variety: 1. has harmful effects on the natural environment, the safety of biological diversity, the agriculture sector, the life or health of humans, animals, or plants, in Egypt; 2. has harmful economic or social effects, hampers local agricultural activities, or it appears that its use is incompatible with the values and beliefs of the community.

used to assess the article 199(2). In this case, the SIA can be used as an important tool to evaluate the implication of granting the new plant varieties.

For article 200, the legislation has directly addressed mechanisms for the problem of bio-prospecting through the use of PIC and BS as can be seen as follows:

> For the article 200, the breeder shall disclose the genetic source relied on to develop the new plant variety. The protection of the new plant variety requires that the breeder has acquired those sources by *legitimate means* under the Egyptian law. Such a requirement extends to traditional knowledge and experience accumulated among local communities the breeder could have relied on in his effects to develop the new plant variety. *Likewise, the breeder who deals with Egyptian genetic sources, with a view to develop new varieties derived therefore shall undertake to obtain the approval of the relevant competent administrative authorities.* He shall also undertake to acknowledge the Egyptian traditional knowledge as sources to what he could have achieved using such knowledge and experience, through the disclosure of the Egyptian source the breeder benefited from, and *by sharing the profits gained with the interested party*, as prescribed in the Regulations of this law.

For the patent part, it provides an indirect condition to deal with the problem of bio-prospecting. In the article 13 under the patent section provides that the patent application shall be accompanied by a detailed description of the invention, including a full statement of the subject matter and of the best way to enable a person of expertise to execute it, and of each product or method for which protection is sought. For the invention involves biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage, the inventor should *have acquired the sources in a legitimate manner*. This requirement is very important for the problem of bio-prospecting because according to the article 16 of the same legislation, it indicates that the Patent office shall grant and publish the application acceptance in the Patent Gazette when the product and process conform with the provisions of the Article 1, 2, and 3 (New, inventive, and industrial applicable) and also satisfied the conditions of the article 12 and 13 for the patent application. Therefore, if anyone could show to the court or the authority that the invention or part of the invention is not legally obtained or illegitimate, then the invention could be revoked. However, with regards to the problem of bio-prospecting, the Egypt shall enact the legislation that control the use of and access to biological resources in order to support the article 13.

7.1.5 The New Plant Varieties Protection Act of Pakistan

For the problem of bio-prospecting, the important tool that deals with the problem of bio-prospecting is on the application. This legislation requires an applicant to file several documents which might be useful for the protection of bio-prospecting problem. Those include a description of the variety in the applicant, as complete as reasonably possible, setting forth its novelty, parentage/pedigree and breeding history. A drawing and photograph to understand and evaluate the novelty of the variety[289] and a written statement of the applicant establishing ownership of the variety, or other necessary explanation of the applicant's right to file the application[290]. In the article 15(d), it seems to be that the requirement to indicate the parental line of the new plant variety and a justification of why the applicant shall be considered as an ownership of a new plant variety can be an important tool for anyone who would like to oppose the right to file of the applicant by using article 40(b)(iii)[291]. However, the opposition might need to show the authority or the court that the applicant should not be a sole ownership of the new plant varieties if the new plant variety is developed from the traditional method or traditional plant varieties by establishing the evidence that the new plant varieties that developed from the traditional variety will harm the public by using the principle of the sovereign rights over natural resources as a key approach for the rebuttal.

In summary, we can see that the countries can design the PVP laws as these 5 PVP laws have addressed conditions for the protection of the problem of bio-prospecting.

7.2 Legislation with regards to the control of and access to biological resources

289 New Plant Varieties Act of Pakistan/ Art 15 (b)

290 New Plant Varieties Act of Pakistan/ Article 15 (d)

291 The Plant Breeders' Rights Office may cancel a Certificate of Plant Breeders' Rights at any time during its term if found that the variety proved harmful to the environment, ecology and public and animal health.

As it can be seen from the analysis of the above PVP legislation, many laws provide clauses and conditions on both the PIC and BS in order to deal with the problem of bio-prospecting. However, it should be noted that nowadays, the development of new plant varieties or the product/ process does not only need to be developed from the plant varieties because the technology can use the other kinds of biological resources.

Therefore, in order to strengthen *sui-generis* legislation, the legislation that deal with the use of and access to the biological resources in each country can be an important source for and directly address to the problem of bio-prospecting because it legitimately can control the use of and access to the biological resources in each country and can also be used to support the other legislation[292]. In addition, it can be seen as an important legislation that hold up in position by serving as a foundation for the invention applies for the patent protection that is derived from the biological resources[293].

The following laws can be seen as important because it is designed to control the access to and use of biological resources and can therefore directly deal with the problem of bio-prospecting. There are different ways and approaches to control the use of biological resources in these legislations. The details of the laws and conditions can be seen as follows:

7.2.1 The Biological Diversity Act of India, 2002

The objective of the biological diversity Act of 2002 is to provide for conservation and sustainable use of its components and equitable sharing of the benefit arising out of the use of biological resources[294]. In order to control and regulate the use of biological resources in India, the Biological Diversity Act has established the National Biodiversity Authority (NBA) to regulate activities such as on the matters relating to the conservation of biodiversity, sustainable use of its components and equitable sharing of benefits arising out of the utilization of

292 This can be seen, for example, the biological resources legislation can support the article 13 of the law on the Protection of Intellectual Property Rights of Egypt.

293 ibid

294 Biological Diversity Act of India 2002/ the Preamble

biological resources, take any measures necessary to oppose the grant of intellectual property rights in any country outside India on any biological resource obtained from India or knowledge associated with such biological resource which is derived from India, and etc. The Act has empowered the NBA to regulate the use of biological diversity in India as can be seen in the Chapter II: Regulation of biological Diversity in section 3:1 as described as follows:

> 3. (1) No person referred to in sub-section (2) shall without previous approval of the National Biodiversity Authority obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio- utilization.

The use of biological resources in India has been protected and regulated by the Biological Diversity Act of India. There are two main conditions those address the problem of bio-prospecting. Those are the Prior Informed Consent and benefit sharing. For the PIC, the Act has directly addressed the problem of bio-prospecting through the PIC by requiring anyone who wants to apply for an intellectual property protection to apply for a product or process based on a use of biological resources obtained from India, then such person must file a permission for a use of biological resources for an intellectual property protection[295].

For the Benefit sharing issue, the Bill has stipulated that the NBA shall be the authority to make benefit sharing arrangement between benefit claimers and a person applying for the use of biological resources[296]. However, it should be noted that the Act does give a lot of power to NBA to make the arrangement in which it might not reflect the need of the local community or the owner of biological resources. The Act

295 Article 6 of the Act: 6. (1) No person shall apply for any intellectual property right by whatever name called in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application: Provided that if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned. (2) The National Biodiversity Authority may, while granting the approval under this section, impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights.

296 Article 21. (1) The National Biodiversity Authority shall while granting approvals under section 19 or section 20 ensure that the terms and conditions subject to which approval is granted secures equitable sharing of benefits arising out of the use of accessed biological resources, their by-products, innovations and practices associated with their use and applications and knowledge relating thereto in accordance with mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefit claimers.

shall stipulate the local community who own the natural resources also has the right to determine the benefit sharing arrangement before approving the use of such biological resources. The Act has stipulated the criteria for equitable benefit sharing (Section 21) which include the terms and conditions for ensuring equitable sharing of the benefit arising out of the use of accessed of biological material, the access shall ensure the conservation and sustainable use of biological diversity through the Ministry of Environment and Forest Notification: In exercise of the powers conferred by Section 62 of the Biological Diversity Act of India, 2002. In addition, in the Ministry of Environment and Forest Notification, it does not stipulate the condition or how the NBA can ensure that the benefit sharing scheme is really reflected the need of the community or the resource own in order to support the previous sentence's justification. This can be assisted by the use of Social Impact Assessment in order to bring the justification for the benefit sharing arrangement.

7.2.2 The National Biodiversity Act of South Africa

The objectives of the National Biodiversity Act of South Africa are to manage, utilize, and conserve the biological diversity in a sustainable manner, to assure the fair and equitable benefit sharing from bio-prospecting among the stakeholders. In the Chapter 6 of the Act: Bio-prospecting, access and benefit sharing, the Act has stipulated the Chapter's objectives which are to regulate bio-prospecting involving indigenous biological resources, to regulate the export from the Republic of indigenous biological resources for the purpose of bio-prospecting or any other kind of research, and to provide for a fair and equitable benefit sharing from bio-prospecting.

With regards to the conditions to control the access and use of biological resources, the Act has used two important mechanisms which are the PIC and BS to ensure that the biological resources are fully protected. For the PIC, the Act has stipulated the procedures to obtain the permit[297] for bio-prospecting, export, and etc both for the normal biological resources and indigenous biological resources. For the benefit sharing scheme, the Act has stipulated that the applicant must enter into the

297 South African Biological Diversity Act/ Section 81

benefit sharing arrangement with the owner of the natural resources for any future benefits.]

The South African Biological diversity Act is the other legislation that addresses the conditions to protect the problem of bio-prospecting. Even though, the BS and PIC scheme has been put into this legislation, however, as previously mentioned that in the BS scheme, there shall be a method such as the SIA to ensure that the BS is justified.

7.2.3 Biodiversity law of the Republic of Costa Rica

The objective of the biological law of Costa Rica is to conserve the biological diversity and sustainable use of the resources as well as to distribute in an equitable manner of benefit and derived costs[298]. In the chapter V of the Act, the Act regulates the access to genetic components and biochemical and protection of associated knowledge. It has recognized the principle of PIC[299] and stipulated the procedure for the access[300]. In addition, the Act has recognized the right to *culture objection* in the article 66. This article has empowered local communities and indigenous peoples to oppose any access to their resources and knowledge for any cultural, spiritual, social, economic, and other motives[301].

In the Section III: protection of intellectual and industrial property rights, the Act has directly addressed the problem of bio-prospecting and intellectual property protection. In the article 79: Congruence of the intellectual property system, the Act has stipulated the any decision taken in the realm of intellectual property protection related to biodiversity must be congruous with the objectives of this law. In addition, the article 80: Obliged prior consultation, the Act has levied the National Seed Office and the Registers of Intellectual Industrial Property to give a prior consultation to the Commission established by this Act before granting any protection of intellectual or industrial property to innovations involving components of biodiversity by providing

298 Biological Law of the Republic of Costa Rica / Article1: Objective

299 Biological Law of the Republic of Costa Rica / Article 63 and 65

300 Biological Law of the Republic of Costa Rica / Article 64 and 69

301 Right to cultural objection: The right of local communities and indigenous peoples to oppose any access to their resources and associated knowledge, be it for cultural, spiritual, social, economic or other motives, is recognized.

the certificate of origin and the Prior informed consent and most importantly, the justified opposition from the Technical Office can prohibit registration of a patent or protection of the innovation.

In addition, the Article 82: Sui Generis Community Intellectual rights has pointed out the very important way of protecting the community intellectual by providing a recognition and protection without any prior declaration or any official registration the knowledge, practices, and innovations of indigenous people and local communities related to the use of components of biodiversity and associated knowledge and thus, the article 82 implies there shall be no form of intellectual property protection regulate the community intellectuals.

The Act has also stipulated methods of determining the appropriateness of nature and scope of community intellectual rights and/ or project that involve with the biological diversity. Such methods seem to be an important method nowadays since the implication of the project and the determination shall not only be left to the authority concerned. The method is the participatory process which has stipulated in the article 83 and 84[302] and public hearing in the article 95[303] as they has been put in the Act for the practitioner to use the method when it involves the community and the resources owner.

In addition, the General Rules for the Access to the Genetic and Biochemical Elements and Resources of the Biodiversity of the Costa Rica, it has stipulated the details of rule for the access to the biodiversity and bio-prospecting including the permits and application for the access. This chapter would like point out that in the article 9[304], it requires the interested party to complete the following documents in order to apply for access permit for bio-prospecting and economic exploitation. Those documents are the application form, technical guideline, Prior informed consent and

302 Article 83- Participatory process to determine the nature and scope of sui generis community intellectual rights. Within eighteen months following the entry into force of this law, the Commission, by means of its Technical Office and in association with the Indigenous Peoples Board and the Small Farmers Board, shall define a participatory process with indigenous and small farmer communities to determine the nature, scope and requirements of these rights for their definitive regulation. The Commission and the organizations involved shall prepare the form, methodology and basic elements of the participatory process.

303 Article 95- Public hearings: When necessary, the National Technical Secretary should carry out public hearings of information and analysis about the actual project and its impact. The cost of publication will be paid for by the interested party.

304 General requirements to apply for access permit for basic research bio-prospecting and economic exploitation

mutually agreed conditions. For the problem of bio-prospecting, the section M[305] of the technical guidelines, it requires an applicant to assess the cultural impact that may arise from the access. In the section k, it requires an applicant to abide submit any agreed terms with the practice or a result of the participatory process as required by the article 83 of the Act.

With regards to the benefit sharing scheme, in the section O of the technical guidelines, it requires an applicant to present the agreed term agreed terms on the equitable distribution of environmental, economic, social, scientific or spiritual benefits, including possible commercial profits at short, mid and long term, of any product or sub product derived from the acquired material and in the article 14 of the General rules has also levied additional criteria for evaluation or approval of the application. One of the conditions is to consider the objectives of conservation, sustainable utilization and fair and equitable distribution of the benefits derived from access to the genetic and biochemical elements and resources and the related traditional knowledge[306].

7.2.4 Costa Rica General Rules for the Access to the Genetic and Biochemical Elements and Resources of the Biodiversity

The Rules for the Access of the Costa Rican Government was written in order to facilitate the Costa Rica Biodiversity Law. In the Rule for the Access, it has divided into three chapters. The first chapter includes the general objective of the Rule for Access and the definition of the important words in order to clarify the meaning of the Costa Rica Biodiversity Law. In the second chapter, this thesis is of the opinion that it can be considered the most important chapter in the Rule for Access because it prescribes requirements and procedures to obtain permits, concessions and agreement for access to genetic and biochemical elements and resources of biodiversity. For example, in the article 9, it is the general requirements

305 Possible risks of environmental or cultural impact that could occur due to access, extraction or processing of the material, due to the granting of the permit applied for access to the resources of biodiversity, such as genetic erosion, biodiversity loss, indirect damage over endangered species or with reduced population or forbidden hunting, or other

306 General Rule for the Access to the Genetic and Biochemical Elements and Resources of the Biodiversity/ Article14 G

to apply for access permit for basic research, bio-prospecting or economic exploitation. It regulates the interested party who would like to get the access to complete the form, technical guidelines, and certain conditions for the permission. For the benefit sharing scheme, the Rule has ruled out for the economic exploitation up to 50% of the royalties obtained by the interested party where the economic exploitation has been carried out. It also provides certain procedure for authorization of permits, follow up and control. For example, in the article 11: Procedure to grant concessions, it informs the applicant that in the cases of granting an access permit for economic exploitation: the interested party has to apply for the access at least six times within a five-year period upon the same genetic or biochemical resource with commercial purposes, getting a concession will be required hereafter. CONAGEBIO's Technical Office will process the application and will remit the file with the respective recommendation, to the Minister's office for its eventual approval and signing.

7.2.5 The Draft of the Biodiversity and Community Knowledge Protection Act of Bangladesh

The draft legislation was submitted by the National Committee on Plant Genetic Resources (NCPGR) in 1998 in order to reaffirm and recognize the sovereign rights of state over the natural resources. In the draft, the draft had strongly recognized the articles in the Convention on biological diversity as well as the Rio declaration for regulating the research, collection, exploitation and use of biological and genetic resources as well as related intellectual knowledge and cultural expressions including the entry of such resources into the country[307]. The draft had stipulated the scope of the draft is to be the principal instrument to guide, inform, determine, control, reinterpret and to give effect, where necessary, to the rights and privileges granted, if any, to new innovations of any form that has used the natural and biological resources including knowledge and culture of the country or of other countries with which Bangladesh has reciprocal recognition of similar Acts, Ordinances or Laws[308] by include all biological and genetic resources and related

307 Draft of the Biodiversity and Community Knowledge Protection Act of Bangladesh / Preamble

308 Draft of the Biodiversity and Community Knowledge Protection Act of Bangladesh / Article 2.3

knowledge[309], however, the draft had given exceptions to the traditional use and exchange of biological and genetic resources as well as related knowledge, culture and practices carried out by and between Communities based upon their customary and traditional practices, particularly Local and Indigenous Communities as well as Communities holding Residual Titles[310].

For the intellectual property protection, the draft act indicated that patenting of life form *is against* the moral intellectual and cultural values of the people of Bangladesh[311] and also prohibits all forms of monopolization of biological and genetic resources and related knowledge and culture[312], however, the exception can be made but it still has to consistent with the provision of the Act.

For the mechanism for the problem of bio-prospecting, in the article 7:4[313]; Prior Informed Consent, the draft act had chosen the PIC as one of the mechanisms to ensure that the sovereign right of state is recognized.

For the benefit sharing, the article 16:6[314] had outlined the benefit sharing arising out of the utilization of biological resources, however, it should be noted that 50% of the profit must be shared with the community might be the obstacle for the private firm to development of product/ process from biological resources in Bangladesh.

309 Article 3.2: This Act shall include all biological and genetic resources and related knowledge as well as their derivatives within the jurisdiction of the country, both in situ and ex situ. It implies all varieties of life forms including plants, animals, fish and aquatic life forms and micro-organisms belonging to all genera/species and varieties, wild or cultivated, occurring naturally or modified in any manner whatsoever through any process, and to their cell lines, genetic material, characteristics, traits, products and the processes involved therein.

310 Draft of the Biodiversity and Community Knowledge Protection Act of Bangladesh/ Article 3.3

311 Draft of the Biodiversity and Community Knowledge Protection Act of Bangladesh/ Art 5.3

312 Draft Legislation on Access to Biological Resources and Community Rights of Pakistan/ Art 5:16

313 Article 7: 4. The biological and genetic resources and the intellectual and cultural knowledge and practices as well as any innovations arising from these shall not be sold, assigned transferred or dealt in any manner without explicit Prior Informed Consent and effective participation of the Communities concerned. The Communities will always have the right to refuse transaction based on gainful intent or any commercial utilization, exploitation and exchange.

314 In addition to fair and equitable benefit sharing in terms of technology transfer and the sharing of knowledge and scientific skills, at least 50 percent of the commercial profit generated in such activities will have to be shared with the Community/ies.

7.2.6 Draft Legislation on Access to Biological Resources and Community Rights of Pakistan

One of the objectives of this Draft Legislation is to be able to protect cultural diversity, valuing the knowledge, innovations, and practices of the local communities and of biological resources; provide adequate mechanisms to guarantee a just, equitable, and effective participation of its biological resources and intellectual resources as well as activities and benefits derived from their utilization, and etc. For the problem of bio-prospecting, the article 4 of the Draft: access to biological resources and related community knowledge and technology has required anyone who would like to access to biological resources must receive a PIC from the competent authority based on mutually agreed terms. For the benefit sharing scheme, the Draft agreement require an applicant to indicate the benefits sharing arrangement which may derive to the country and the concerned local communities. With regards to the intellectual rights, the article 4.6 of the draft has stated that any biological resources or the derived product or the process obtained and used in the violation of the provisions of the act shall not be recognized and may not be able to claim for the intellectual property protection.

With regards to the community rights, the Article 5: a community right of the Draft has specified the rights of the communities to give the prior informed consent for any knowledge, innovations, or practices. In addition, it also requires the competent authority to establish regulatory measures *through a process of consultation and participation of the local communities.* In addition, the Draft has also ensure that the local communities have the right not to allow the collection of the biological resources and access to their traditional technologies, knowledge, innovations, and practices.

7.2.7 The Community Intellectual Rights Protection Act of the Philippines

This legislation has recognized in the section two that the rights of the owner including indigenous peoples and local communities over genetic resource, traditional medicines, agricultural methods and local technologies. This legislation has

recognized the PIC and BS mechanisms to deal with the problem of bio-prospecting[315].

7.2.8 The implementing rules and regulations on the prospecting of biological and genetic resources of the Philippine

Pursuant to Section 15 of Executive Order No. 247 dated 18 May 1995 otherwise known as "Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, Their Byproducts and Derivatives, For Scientific and Commercial Purposes, and for Other Purposes", this Administrative Order has set the rules and regulations governing the implementation of the Order.

The purpose of this Order is to provide the detail of the processes for the institutions and agencies concerned to regulate the research, collection, and use of biological and genetic resources. In this rules and regulations, it has addressed the problem of bio-prospecting by requiring the PIC mechanism with the customary traditions, practices of the concerned communities and, where appropriate, concurrence of the Council of the Elders in a public consultation/meeting in the site concerned[316]. The participatory approach of the owner of resource has been given an importance as can be seen in the section 6: requirements and procedures for application and processing of research agreements. In the section 6.1.3, the supporting document shall include the PIC certificate in which this certificate must come from different places depends upon where the biological resources come from[317]. This point is very important because it recognizes the ownership of the

315 Community Ownership of Traditional Knowledge – All benefits arising from the knowledge and innovations by indigenous and local communities should accrue to their development and welfare and should therefore be equitably shared. Any commercial utilization of such knowledge and innovations should be made only with the free and informed consent of its genera1 owners or custodians under terms mutually agreed upon. The State shall also strive to protect and encourage the customary use of biological resources in accordance with traditional cultural practices which are compatible and which promote conservation and sustainable use.

316 Section 5.2 of the implementing rules and regulations on the prospecting of biological and genetic resources.

317 6.1.3. Prior Informed Consent (PIC) Certificate obtained in accordance with Section 7 hereof from the following: a)Indigenous Cultural Communities/Indigenous Peoples (Imps) - in cases where the prospecting of biological and genetic resources will be undertaken within their ancestral domains/lands ;b)Local Communities (LC) - in cases where the prospecting of

resources owner. It does not give the full power to any authority to authorize the PIC. All of which will lead to the benefit sharing scheme between the party concerned. However, it would be better if the law does stipulate the BS scheme in the Rules in order to assure the law does provide a compulsory requirement for the bio-prospector and resources owner to follow the suit.

7.2.9 Draft Guyana Environmental Protection (Bio-prospecting) Regulations 2001

The Draft Guyana Regulations is similar to the Costa Rica General Rules for the Access to the Genetic and Biochemical Elements and Resources of the Biodiversity because its main objective is to regulate and control the bio-prospecting activities in Guyana. The Draft Regulations has divided into seven sections which are application for research agreement, procedure for processing application, minimum terms and conditions for a research agreement, reports and records, collecting and export specimen, return of specimen, and offences and penalties. For the problem of bio-prospecting, it refers in the procedure for processing application. It requires the bio-prospector to enter the agreement with the authority concerned, have a meeting with the local community and competent agency, pass the EIA if it requires, and lastly to share the benefit arising out of the utilization of biological resources[318].

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biological and genetic resources will be undertaken within their area/s of jurisdiction; c)Protected Area Management Board (PAMB) - in cases where the prospecting of biological and genetic resources will be undertaken within a protected area. Provided that, if the PAMB for a certain protected area has not been organized, a letter of consent shall be obtained from the concerned Regional Executive Director under whose jurisdiction the protected area is located; d)Private Land Owner - in cases where the prospecting of biological and genetic resources will be undertaken within the private land.

318 Benefit Sharing: 17. Every Research Agreement shall include provisions for the payment for an agreed part of any financial gain, including royalties derived from research and/or development of any biological or genetic material taken from Guyana, to the Government of Guyana, local or indigenous cultural community, individual person or designated beneficiary in the event that a commercial application is discovered.

Profits form commercial use: 18 Where commercial applications are developed with regard to specimen that was collected in Guyana, the parties to the agreement shall identify the Government of Guyana among the parties which shall be entitled to share in any profits that may be derived and shall consent to an independent public accountant examining the books and records as are necessary to ensure that payment is in accordance with the financial agreement that was arranged.

7.2.10 Indian Biodiversity Rule 2004

The main objective of the Indian Biodiversity Rule is to exercise the power given in the Indian Biodiversity Act and put the power of the National Biodiversity Authority into practice. The Rule has been divided into two parts. The first part is about the power, function, and responsibility of the National Biodiversity Authority and the second part is about the problem of bio-prospecting. For the second part, the Rule has set the procedure for access the biological resources and traditional knowledge, revocation of access or approval[319], restriction on activities relates to access to biological resources[320], procedure for seeking prior approval before applying for IPRs[321], criteria of benefit sharing[322] and etc.

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319 (1) The Authority may either on the basis of any complaint or suo moto withdraw the approval granted for access under rule 15 and revoke the written agreement under the following conditions, namely:

(i) on the basis of reasonable belief that the person to whom the approval was granted has violated any of the provisions of the Act or the condition on which the approval was granted; (ii) when the person who has been granted approval has failed to comply with the terms of the agreement; (iii) on failure to comply with any of the conditions of access granted; (iv) on account of overriding public interest or for protection of environment and conservation of biological diversity.

(2) The Authority shall send a copy of every order of revocation issued by it to the concerned State Biodiversity Board and the Biodiversity Management Committees for prohibiting the access and also to assess the damage, if any caused and take steps to recover the damage.

320 (1) The Authority if it deems necessary and appropriate shall take the steps to restrict or prohibit the request for access to biological resources for the following reasons; namely:

(i) the request for access is for any endangered taxa; (ii) the request for access is for any endemic and rare species; (iii) the request for access may likely to result in adverse effect on the livelihoods of the local people; (iv) the request to access may result in adverse environmental impact which may be difficult to control and mitigate; (v) the request for access may cause genetic erosion or affecting the ecosystem function; (vi) use of resources for purposes contrary to national interest and other related international agreements entered into by India.

321 (1) Any person desirous of applying for a patent or any other intellectual property based on research on biological material and knowledge obtained from India shall make an application Form III. (2) Every application under sub-rule (1) shall be accompanied by paying a fee of five hundred rupees. (3) The Authority after due appraisal of the application and after collecting any additional information, on the basis of merit shall decide on the application, as far as possible within a period of three months or receipt of the same. (4) On being satisfied that the applicant has fulfilled all the necessary requirements, the Authority may grant approval for applying for a patent or any other IPR subject to such terms and conditions as it may deem fit to impose in each case. (5) The approval shall be granted in the form of a written agreement duly signed by an authorized officer of the Authority and the applicant. The form of the agreement may be decided by the Authority. (6) The Authority may reject the application if it considers that the request cannot be acceded to after recording the reasons. Before passing order of rejection, the applicant shall be given an opportunity of hearing.

322 (1) The Authority shall by notification in the Official Gazette formulate the guidelines and describe the benefit sharing formula. (2) The guidelines shall provide for monetary and other benefits such as royalty, joint ventures, technology transfer, product development, education and awareness raising activities, institutional capacity building and venture capital fund.

(3) The formula for benefit sharing shall be determined on a case-by-case basis. (4) The Authority while granting approval to any person for access or for transfer of results of research or applying for patent and IPR or for third party transfer of the accessed

7.2.11 Brazil Provisional measure on access to genetic resources and traditional knowledge

This measure was written to regulate access to the genetic heritage, protection of and access to associated traditional knowledge, sharing of benefits and access to and transfer of technology for their conservation and use of biological resources. The measure has been divided into different chapters. The main chapters for the problem of bio-prospecting are in chapter I, X, XII. In the chapter I, it refers to the general provisions of the benefits, rights and obligation concerning access to biological resources and etc. In the Chapter X, it refers to the access to components of the genetic resources within the national territory must receive prior authorization. In the Chapter XI, it refers to the benefit sharing arrangements. In this chapter, it provides that the benefits arising from economic exploitation of a product or process developed from samples of components of the genetic heritage and associated traditional knowledge, obtained by a national institution or an institution with its headquarters abroad shall be shared in a fair and equitable way between the contracting parties, as provided in the regulations and relevant legislation.[323]

7.2.12 Pakistan Draft Law on access to biological resources and community rights

The main objectives of this law are to ensure and support the rights of local communities over biological resources and their knowledge, the conservation and sustainable use of biological resources and knowledge and provide an appropriate

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biological resource and associated knowledge may impose terms and conditions for ensuring equitable sharing of the benefits arising out of the use of accessed biological material and associated knowledge. (5) The quantum of benefits shall be mutually agreed upon between the persons applying for such approval and the Authority in consultation with the local bodies and benefit claimers and may be decided in due regard to the defined parameters of access, the extent of use, the sustainability aspect, impact and expected outcome levels, including measures ensuring conservation and sustainable use of biological diversity. (6) Depending upon each case, the Authority shall stipulate the time frame for assessing benefit sharing on short, medium, and long term benefits. (7) The Authority shall stipulate that benefits shall ensure conservation and sustainable use of biological diversity. (8) Where biological resources or knowledge is accessed form a specific individual or a group of individuals or organizations, the Authority may take steps to ensure that the agreed amount is paid directly to them through the district administration. Where such individuals or group of individuals or organizations cannot be identified, the monetary benefits shall be deposited in the National Biodiversity Fund. (9) Five percent of the assessed benefits shall be earmarked for the Authority or Board as the case may be, towards the administrative and service charges. (10) The Authority shall monitor the flow of benefits as determined under sub rule (4) in a manner determined by it.

323 Pakistan Draft Law on access to biological resources and community rights/ Art 24

system of access to biological resources based upon mutually agreed terms and subject to the prior informed consent and lastly to promote appropriate mechanisms for a fair and equitable sharing of benefits arising from the use of biological resources. In order to bio-prospect the biological resources, the draft stipulates the access to biological resources shall be based upon mutually agreed terms and subject to the prior informed consent of the State or competent authority[324]. For the benefit sharing scheme, the Draft has stipulated that the State shall recognize and protect the rights of the local communities to collective benefit from their knowledge, innovations and practices acquired through generations (past, present and future) and to receive compensation for the conservation of biological resources in accordance with the provisions of this legislation and subsequent regulations[325] and the State shall ensure that at least 10 percent of benefit obtained from any commercial use of biological resources are paid to the concerned local communities[326].

7.2.13 African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological resources

In the African Model Legislation, the Model has outlined the rules and regulations regarding access to biological resources, community and farmer's rights, and plant breeders' rights.

With regards to the access to biological resources, the Model requires a written prior informed consent of the National Competent Authority and the concerned local communities for any access to biological resources. In addition, the model recommends the National Competent Authority to consult with the local community in order to ascertain their consent and grant for any access and if there is no consultation, then the access to biological resources shall be deemed to be invalid. In the Part V: Community Rights, the model recognize *the right to refuse* consent and access and right to withdraw or place restrictions on consent and access.

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324 Pakistan Draft Law on access to biological resources and community rights/ Art 4

325 Pakistan Draft Law on access to biological resources and community rights/ Art 5.1

326 Pakistan Draft Law on access to biological resources and community rights/ Art 5.4

For the benefit sharing, the model states that the benefit arising out of the use of biological resources both commercially and non-commercially will be entitled to a share of the earning. In the Part V: Community rights, the model recommend the right of the community to fully participate and approve of the benefit sharing arising out of the legitimate custodians and users of their biological resources.

However, with regards to the patents over life forms and biological processes, the model recommends the patents over life forms and biological processes cannot be applied for. On this recommendation, it will definitely violate the TRIPs agreement in particular article 27.b and most importantly, it will slow down the development of biological product and process in the countries where adopt this recommendation.

It seems to be that African Model has directly addressed the problem of bio-prospecting, however, as previously mentioned that the model does not mention any method or mechanism to justify *the right to refuse.* In addition, the South African legislation was written to recognize the rights of the local communities and to regulate the access to biological resources, as a consequence, it is different from the India biological Act because the main objective of the African Model is to uphold the principle of sovereign rights of state whereas the main objective of India Biological Resources is to maximize the utilization of resources. However, both legislations can still use to address the problem of bio-prospecting. It is depend upon the country whether they can choose either one of them or both to address the bio-prospecting problem.

7.2.14 The ASEAN Framework Agreement on access to biological and genetic resources

The ASEAN Framework was written in order to encourage the member of ASEAN countries to recognize the sovereign right of state and the value of the genetic resources in the community. The ASEAN framework has recognized that the PIC and BS scheme are important condition for the bio-prospecting problems. For the PIC mechanism, the agreement has states in the article 10[327]. In addition, in the article 10,

327Article 10: The Member States shall provide in their access regulations that each application for prior informed consent shall be accompanied by a full disclosure of the following information: name of the researcher, collector or collaborator; specific area and location of the bio-prospecting activity; the defined period when the collection activities will take place; the specific

it has assured the participation of the local community in the procedure of granting the PIC[328]. This can be seen as a guarantee clause for the local community to have their participation when their biological resources or local knowledge in which they have been involved with has been filed for the intellectual property protection. For the benefit sharing scheme, the agreement has stipulated the involvement of the resources owner in the BS negotiation process and a full disclosure of any benefits and risks involving with the use of the resource[329]. This can also be a guarantee clause for the ASEAN members to include the participation of resource owner not only for the authority concerned to make the final decision on benefit sharing.

It should be noted that the ASEAN Framework has strengthen the participation of the resources owner to determine the access and use of their biological resources including the benefit sharing arrangement. Therefore, it is necessary for the member of the ASEAN to also find a condition in which help the authority concerned and local community to quantify and quality the potential benefit and cost of granting an access and benefit arising out of utilization of biological resources. The answer could be the use of the Social Impact Assessment.

7.2.15 The Model law for the Protection of Traditional Ecological knowledge, innovations, and practices of Pacific Island countries

In this model, it has also recommended to use the PIC and Benefit sharing scheme for the problem of bio-prospecting as can be seen in the section 10[330]. In

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purposes, objectives, resources to be used, activities and methodologies, expected outputs and other related information; information on the local collaborator; information on the potential environmental and ecological impact of the bio-prospecting activity; and potential benefits to the country.

328 Article 10: The procedures leading to the grant of prior informed consent at the local level shall provide for the active involvement of indigenous peoples and local communities embodying traditional lifestyles. The prior informed consent process shall respect and comply with the customary laws, practices and protocols of indigenous peoples and local communities and the disclosure of any information pertaining to the access shall be in a language understandable to the local communities.

329 Article 11 - Fair and Equitable Sharing of Benefits: shall be actively included in the negotiation of benefits on the basis of a full disclosure of potential benefits and risks arising from the use of the resource. Any benefit sharing arrangements that may be entered into shall not negatively interfere with traditional knowledge systems and practices of indigenous peoples and local communities.

330 Any person using or proposing to use traditional ecological knowledge, or an innovation or any part of such innovation, or a practice for commercial use must: (a) seek the prior informed consent of the owner, where there is one, or co-owners where there are several, of the knowledge, innovation or practice; and (b) enter into an access and benefit sharing agreement with the owner or co-owners.

addition, this model still recommends the Pacific Island Countries to amend the patent law by adding the PIC and BS mechanism as a requirement in the application form for the innovation which use the traditional innovation and knowledge[331]. It can be seen that the biodiversity law that many countries have introduced may be called different names and have several objectives such as the conservation, the utilization of resources, endangered species, or the control of the use of natural resources. However, one of the common objectives of the biodiversity legislation is to be able to control the access to and the use of the biological resources. For the control of the use of natural and biological resources in the biodiversity law, there are common procedures and objectives. Those are, for example, establishing the obligation to sign a Contract of Access between the applicant and the State to acquire genetic resources, determines the obligations and rights of the contracting parties[332], manage and conserve the biological diversity and its component in a sustainable manner and fair and equitable sharing among stakeholders of benefits arising from bio-prospecting[333], the conservation of biodiversity and the sustainable use of the resources as well as to distribute in an equitable manner the benefits and derived costs [334], to provide for conservation and sustainable use of its components and equitable sharing of the benefit arising out of the use of biological resources[335]and etc.

In order to deal with the biodiversity issue, the law usually establishes or assigns to have an Authority to implement the provision of the law. The duty of the institute can be seen, for example, to implement and enforce the regulation, the legal and contractual conditions for the access to genetic resources, its derivatives or their associated intangible components and other connected legal dispositions[336], or to formulate, define and implement national policies relating to the conservation,

331 Patent law is to be amended by making changes to the following effect: (a) An applicant for a patent, or a holder of an overseas patent seeking registration of that patent in this country, must provide clear evidence to the Patent Office that if the invention for which a patent is being sought had used or was based upon traditional ecological knowledge, a traditional innovation or a traditional practice that the prior informed written consent of the owner was obtained, an arrangement had been made as to access and benefit-sharing, and the owner's permission was obtained to seek a patent. Lack of such evidence will result in rejection of the application. (b) An existing patent is revocable if it is found to have used or been based upon traditional ecological knowledge, a traditional innovation or a traditional practice but had not satisfied the requirements of paragraph (a).

332 Bolivia Regulations of Decision 391 on the Common Regime for Access to Genetic Resources

333 Biodiversity Act of 2004 of the South Africa

334 Costa Rica Biodiversity Law

335 Preamble of the Biodiversity Bill of India

336 Bolivia Regulations of Decision 391 on the Common Regime for Access to Genetic Resources/ Art 5a

sustainable use and development of existing genetic resources in the national territory[337], to formulate and coordinate the policies for access to the components of biodiversity and associated knowledge in order to ensure adequate scientific and technical transfer and the proper distribution of the benefits[338].

7.3. Summary

All the above important illustrations can be seen as important tool and requirement for the protection of the bio-prospecting problem. In order to do so, as mentioned, the mentioned formal conditions and tools can be enacted in a new legislation that directly deal with the access to and use of biological resources and as a consequence, all the formal conditions and tool can be put into one legislation as "an one-stop requirements" that the bio-prospector must follow. It can be seen that there are many PVP and biological law are designed and has been used for the protection of the bio-prospecting problem. As from the above legislations, there are several points those seem to be able to deal with the problem of bio-prospecting as can be summarized as follows:

7.3.1 New Legislation

In order to deal with the problem of bio-prospecting efficiently and effectively, there should be a new legislation such as the biological resources legislation that design to deal with the problem of bio-prospecting in order to support as a legitimate and legal mean for the recognition of the sovereign right of state.

7.3.2 A section in the biodiversity legislation that refers to a grant of an intellectual property protection for the product and process that derives from the biological resources.

This can be understood that there are not many countries that mention intellectual property protection in the biological resources legislation because they

337 Bolivia Regulations of Decision 391 on the Common Regime for Access to Genetic Resources/ Art 5b

338 Costa Rica Biodiversity Law/ Art 14:5

have been considered to be two separate issues. However, because of the rapid change of the technologically and scientifically development and rigid of intellectual property law in particular the patent law, many countries have started to put the clause for intellectual property protection in the biological legislation in order to address the problem of bio-prospecting. In those legislations, the biological legislation has indicated that without the permission of the use of biological resources and any benefit agreement arising out of the use of biological resources, no one can be able to apply the product and process for the intellectual property protection for the innovation that derived from the utilization of biological resources. As a consequence, the request of any intellectual property protection for a product and process that develop from the biological resources in particular patent protection should be required to meet a standard set by the Biological legislation.

7.3.3 Prior informed consent

The access to and the use of biological resources both commercially and non-commercially shall require a written consent from the owner or the authority concerned. The objective of the PIC is to be able to control the use of biological resources by requiring a permit to use of such resources. This mean that if anyone who like to use of their biological resources, then he or she need to request an authority concerned or to the community who recognize by law as a owner of natural resources and submit the PIC with the application to the authority concerned for a permission[339],[340].

339 Bolivia Regulations of Decision 391 on the Common Regime for Access to Genetic Resources/ Art 17 : The requests for access to genetic esources to which Article 2 of the present Regulation refers impetrates by natural persons or legal foreigners must be submitted to the Competent National Authority. Natural persons or legal nationals, that intend to access any genetic resource to which Article 2 of the present Regulation refers, must present his Requests of Access before the Departmental or National Authority, according to his advice, when the access activities are made in the jurisdiction of a single Department. When the Request involves access activities in the jurisdiction of more than one Department, the Request must be submitted to the Competent National Authority.

340 Costa Rica Biodiversity Law/ Art 63:1 : Prior Informed Consent of the representatives of the place where the access will occur, be they the regional councils of Conservation Areas, the owners of farms or the indigenous authorities, when it is in their territories.

7.3.4 Benefit sharing schemes

The objective of BS schemes is to recognize the sovereign rights of the country and right to be rewarded for the contribution made by the community. In the biological legislations and in the PVP legislations, the applicant should be required to submit the BS agreement between the applicant and the owner of the resources along with the application for a permit to use and access or for the grant of plant variety protection respectively. In some legislation, the details of the benefit sharing agreement are done privately whereas in the other legislations, the details of the benefit sharing agreement are prescribed in the biological legislation. All of these will be submitted to the authority concerned for the approval of granting the intellectual property protection for the product/ process derived of biological resources.

7.3.5 The Social Impact Assessment:

In biodiversity legislation, SIA provides a method that can ensure the transparency and accountability of the participatory approach. The SIA can be used as a condition that can keep the existing and arising issues those relevant to IPRs scheme up to date and make it flexible enough for the country to prevent the harm to occur. It should be understood that the SIA is not the answer for the problem of bio-prospecting but it is a tool to identify the problems and to determine an appropriate answer for the office to grant the permission to access or to utilize any biological resources or for the community or authority concerned to justify and weigh the benefit arising out of the utilization of biological resources of the community.

7.3.6 The application:

The application for the access and utilization of biological resources is a very important tool to deal with the problem of bio-prospecting because the application shall require the applicant to complete and submit the requested information. All information requested must be accurate, reliable, and justifiable because disclosing false information can cause the application to be invalid.

7.4 Conclusion

In conclusion, it can be seen that the Biological Legislation can be seen as one of the important tools to deal with the problem of bio-prospecting. The important conditions, institutional setting, and other requirements can be designed to cope with the bio-prospecting problem. It can be seen that the two mentioned conditions and tool can be used for the bio-prospecting problem. For the PIC and BS, they are clearly accepted as conditions which can be used for the bio-prospecting problem. There are two options to put these conditions either as criteria of patentability or in a new legislation which directly address the bio-prospecting problem. For the option to put it in criteria of patentability it might be politically difficult as mentioned in the previous chapter, therefore, to put in the Biodiversity Legislation might the only option left in order to control the use and access of the biological resources. For the SIA, it seems to be that it is up to country how the SIA would be used. The SIA can be used as a problem identifier whether the authority shall grant the use and access of the biological resources or to use it as a condition to justify the Benefit sharing scheme or both in which it is all depend on the member to see which option would be of best benefit for the country.

It is argued here that it would be in the best interest of the developing nations to put the conditions and tool in a separate legislation because of two important reasons. The first reason would be to escape the rigidly written clauses of the TRIPs agreement and the political difficulties of achieving change at the WTO. The second reason would be the new legislation can be written and enacted in order to control the access and the utilization of the biological resources in the country, therefore, it would be faster for the country to introduce, revise, and regulate the use of their biological resources.

The next chapter will examine the bio-prospecting problem in the context of Thailand, a developing country which possesses abundant biodiversity, and explain how the Thai authorities could deal with the problem of bio-prospecting legally and systematically.

Chapter 8: Thailand a case study

This thesis has addressed the problem of bio-prospecting by looking at IPRs, in particular the patent law and biodiversity legislation in a coordinated way. A coordinated way means keeping a balance between the legitimate rights of the innovator, the recognition of the sovereign right of states over their biological resources, and the international commitments under the international law. Therefore, this chapter will examine how the recommended conditions and tool discussed in the previous chapters can be introduced in biodiversity legislation in order to address the bio-prospecting problem in Thailand.

This chapter will be divided into three sections. The first section will discuss a general picture of and the importance of biodiversity in Thailand. The second section will discuss Thailand's legal obligation with regards to the problem of bio-prospecting in domestic law. The third section will discuss how the recommended conditions could be introduced in Thailand's biodiversity legislation.

8.1. A general picture of Thailand and the importance of biodiversity in Thailand

8.1.1 Why choose Thailand as a case study?

There are two main reasons why this thesis has chosen Thailand as a reference. The first reason to be shown in details in the next section is that Thailand is located in the tropical zone country in which geographically it gives Thailand a place with abundant biological resources. The second reason is Thailand as happens to many countries is still not properly equipped with the legal tools to deal with the problem of bio-prospecting domestically. As a consequence, it is necessary to examine how Thailand can legally acquire and use the conditions and tools to deal with the problem of bio-prospecting.

8.1.2 General Information of Thailand

The Kingdom of Thailand, previously known as Siam, is situated in the heart of Southeast Asia with Bangkok as the capital city. It shares borders with Myanmar to the east, Laos to the northeast, Cambodia to the west, and Malaysia to the south. Thailand is around 198,114 square miles, or roughly the size of France. The Kingdom borders two bodies of water—the Gulf of Thailand to the south and the Indian Ocean to the west. Thailand has a warm and tropical climate. As of 2004, the population of Thailand stood at around 65 million and about 10 million of whom live in the capital city of Bangkok. The largest ethnic minority is the Chinese and the official language is Thai. Buddhism is the faith of approximately 95 percent of the population. His Majesty the King as the head of state, head of armed forces, and upholder of Buddhism and all other religions.

8.1.3 Legal System in Thailand

Since 1932, Thailand has chosen a constitutional monarchy system, with a king as a head of state and a parliamentarian form of government. Thai governmental structure consists of three key components. The first is the executive branch. Under the constitution, the prime minister who comes from the lower house is a head of executive branch. The second component is the legislative branch. The constitution stated that the National Assembly consists of the two categories of members: the House of Representatives (the lower house) and the Senate (the upper house). The bicameral parliament is represented of 500 MP and 200 senators. The third component is the judiciary branch. Thai judiciary was found upon the concept of a civil law system. Thai administration of justice and its machinery are organized through written legislation. All case proceedings, execution of law, and the safeguarding of justice must solemnly conform to promulgated laws, including government rules and decrees. According to the Law Governing Court Organization Act of 1934 revised in 1998, there are three levels of courts were established which are the Courts of First Instance, the Courts of Appeal and the Supreme Court. There are about 135 courts of First Instance throughout the kingdom. In Bangkok Metropolis, the Court of First Instance include Civil, Criminal, and the specialized

court such as the Central Juvenile Court, the Central Labour Court, the Central Intellectual Property and International Trade Court (CIPITC), and Central Tax Courts, as well as District Courts which have jurisdiction over minor cases. In the provinces, Courts of First Instance include Provincial Juvenile, and District Courts. Courts of Appeal consist of one Bangkok-based Court of Appeal and three Regional Courts of Appeal. There is one Supreme Court with jurisdiction to review and adjudicate all cases, and the Court's judgments are final. It should be noted here that, as of 1999, all the intellectual property disputes will go directly to the CIPITC. For the intellectual property case, the CIPITC has its own appeal procedure therefore, the appellate will not go the court of Appeal, however, the Supreme Court still make the final decision for the case[341].

8.1.5 The importance of Biological Diversity in Thailand

Thailand is situated in the tropical forest area around the equator zone at approximately 23 North. Thailand is consisted of many kinds of biological resources including mammals, birds, reptiles, amphibians, fishes, floras and plants. In 1896, the forest area was accounted for 70% of the territorial land but because of the development of economy and the logging business, in 1997, the forest areas have reduced to 30%[342]. Ecologist generally agreed that there are 5 millions types of habitat in this world and in Thailand itself, there are approximately 7% of the 5 millions types of habitat[343].

8.1.5.1 Plants[344]

Thailand harbours one of the richest floras on earth, with an estimated 1,900 genera and 10,000 species of vascular plants. 756 species are endemic including 87 species of orchids and many of them are known only form one or a few localities.

341 The Central Intellectual Property and International trade Court, www.cipitc.or.th (13 March 2009)

342 Information available at www.moac.go.th (Ministry of Agriculture and Cooperatives, Royal Thai Government)

343 ,SrinakarinViroj University: Biological Diversity: Social Development according to the Royal Guidance, November 2000 p. 17

344 Office of Natural Resources and Environmental Policy and Planning, Royal Thai Government: Thailand Red Data: Plants; 2006

Wealth of Thai flora is due to the fact that the country is positioned at a unique crossroads of three main floristic regions namely, Indo-Himalaya, Indo-China, and Malaysia. Currently the work on the Flora of Thailand has so far enumerated only about 50 percent of total country's flora or approximately 1,400 species are records and many more new records can be expected.

8.1.5.2 Mammals, Reptiles and Amphibians, and birds[345]

The status of mammals, reptiles, and amphibians, there are 302 species of mammals, at least 350 species of reptiles, and 137 species of amphibians. A total of 302 species of mammals, 5 are endemic. A total of 350 species of reptiles, 47 species are endemics. A total of 137 species of amphibians, 7 species are endemic. For birds, Thailand has 982 species of birds, two bird species are endemic

However, it should be noted that there is neither a study indicating the importance of bio-prospecting to the Thai economy nor statistical data indicating how much the company has used the biological resources for commercial explorations in Thailand. However, it should be noted that in 2002, Thailand's GDP was approximately $130 billion in which 10% of the GDP directly came from the agriculture sector or 30% of the GDP came from the agro-industry[346]. The bio-technological product and process has been using in Thailand in the past twenty years especially in the agriculture sector where at least 60% of Thai population live on. Unfortunately, there has not been any study indicating and classifying the commercial use of biological product and process in Thailand since most of the information on the use and market value of the product and process have been classified by the private sector and there was not many academic interested to conduct their research on the use and market value of the biological product and process.

345 Office of Natural Resources and Environmental Policy and Planning, Royal Thai Government Thailand Red Data: Mammals, Reptiles, Amphibians, and Bird; 2005

346 NESDB stands for the National Economic and Social Development Board : www..nesdb.go.th (9 January 2007)

8.2: Thailand's legal obligation with regards to the problem of bio-prospecting in domestic law

Internationally, Thailand has been a member of the WTO since 1995 and parties to CBD since 2006. Thailand has domestically taken legal obligations with regards to the problem of bio-prospecting both prior and after Thailand became the member of the TRIPs agreement and parties to the CBD. Those legal obligations can be divided into three categories.

8.2.1 Legislation that relates to the access and use of biological resources.

The first category of legislation can be seen in the Plants Act B.E. 2518 (1975) and the Wild Life Protection Act B.E. 2535 (1992). For the Plant Act B.E. 2518 (1975), one of the objectives of this Act was written to prohibit the collection, sell, importation, exportation, or carry across plant, controlled plant/ seed, prohibited plant/seed, registered varieties/seed, and reserved plant/seed without permission as stated in the first section of the section 14 of the Act[347]. The objective of this Act was written in order to protect the plant and its seed which can be stolen for sell or export without any permission from the authority in particular the wild orchid and rare plants. However, it should be noted this Act was enacted long before the problem of bio-prospecting has become an issue therefore, this Act does not have any section that deal with intellectual property protection. For the Wild Life Protection Act B.E. 2535 (1992), The Act was written for the protection of the protected and wild life animal in the protected area in which prohibit people to hunt, keep, import, and export the entire wild life animal as listed in the annex without permission. This legislation was enacted in order to comply with the CITES convention[348].

347 This section stated that "A person shall not collect, sell, import, export, or carry across controlled plants/ seeds for commercial purpose unless he has received a license from the competent official and must store controlled plants in a place for storing controlled plants/ seeds as specified in the license.

348 Thailand entered into force with the CITES on 21/4/1983

8.2.2 Legislation that protects biological diversity according to the geographical and legally-defined boundaries.

The second category of legislation includes the National Reserved Forest Act of 1964, the National Park Act of 1961, the Forest Act of 1941, the Wild Animal Reservation and Protection Act of 1992, the Fishery Act of 1947, the Animal Variety Promotion Act of 1966. With regards to the problem of bio-prospecting, all of these six legislations have indicated that the use of biological materials obtained from protected areas in the legislations shall receive permission first before using it both for the commercial and non-commercial use. One of the objective of these legislations is to be able to control and monitor the activities occurred and the use of natural resources in the protected areas because the law want to prevent anyone to steal or make any wrongdoing in the protected areas where contain abundant natural resources. However, these legislations do not indicate any clause that deal with the problem of bio-prospecting.

8.2.3 Legislation that relates to the intellectual property protection.

The third category of legislation includes the Patent Act B.E. 2522 (1979) as amended by the Patent Act (No.2) B.E 2535 (1992) and the Patent Act (No.3) B.E. 2542 (1999) and the Plant Varieties Protection Act B.E. 2542 (1999).

8.2.3.1 Thailand has enacted the Patent Act since 1979; however, the recent amendment which was in 1999 was done in order to conform to the TRIPs agreement. According to the criteria of patentability of Thai Patent Act, the Act has stipulated that according to section 5 Subject to Section 9, a patent may be granted only for an invention in respect of the invention is new[349]; it involves an inventive step[350]; and it

349 Section 6(1) defined the word "new" as the product or process does not form part of the state of the art. The state of art also includes any of the following inventions: an invention which was widely known or used by others in the country before the date of application for the patent; an invention the subject matter of which was described in a document or printed publication, displayed or otherwise disclosed to the public, in this or a foreign country before the date of the application for a patent; an invention for which a patent or petty patent was granted in this or a foreign country before the date of application; an invention for which a patent or petty patent was applied in a foreign country more than eighteen months before the date of the application and a patent or petty patent has not been granted for such invention; an invention for which a patent or petty patent was applied

is capable of industrial application[351]. In addition, as revised by the Patent Act (No.2) B.E. 2535 and the Patent Act (No.3) B.E. 2542 Section 9(1), the Act stipulated that the following inventions are not protected under this Act: naturally occurring micro-organisms and their components, animals, plants or extracts from animals or plants; Scientific or mathematical rules or theories; Computer programs; Methods of diagnosis, treatment or cure of human and animal diseases; and Inventions contrary to public order, morality, health or welfare. The act does not stipulate any clause or exceptions to deal with the problem of bio-prospecting. This can be seen that Thai Patent Act is not different from the TRIPs agreement and does not provide any clause or conditions to deal with the problem of bio-prospecting.

8.2.3.2 The Plant Varieties Protection Act was enacted in 1999. Since Thailand is not member of UPOV, therefore, Thailand has chosen to write her own law with regards to plant variety protection or so called sui generis system in order to be conformed to the TRIPs agreement[352]. The objective of this Act was written for two main reasons. The first reason is to prescribe regulations with regard to the studies, experimentation, research, breeding, development, intellectual property protection of or into plant varieties from new plants varieties, local domestic plant varieties, general domestic plant varieties and wild plant varieties. For the second reason is to prescribe regulations with regard to the management of the Plant Varieties Protection Fund. The descriptions of new plant variety are similar to the UPOV

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for in this or a foreign country and the application was published before the date of application. A disclosure which was due to, or made in consequence of, the subject matter having been obtained unlawfully, or a disclosure which was made by the inventor, or made in consequence of, the inventor displaying the invention at an international exhibition or an official exhibition if such disclosure was done within twelve months before the filing of an application for the patent, shall not be deemed to be a disclosure under subsection (2) above.

350Section 7 An invention shall be taken to involve an inventive step if it is not obvious to a person ordinary skilled in the art.

351 Section 8 An invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including handicrafts, agriculture and commerce.

352 With regards to the biotechnology, there is no specific law or directive which regulates the exploitation of biotechnological product and process except as stated in the patent Act. The development of biotechnological product and process has been promoted and financially supported through National Centre for Genetic and Bio-technology Centre (BIOTEC). The BIOTEC is part of the Ministry of Science and Technology in which their main goal is to conduct a research on biotechnology. It shall be noted here that nowadays, the government does not allow the private and public sector to commercialize and import the GM products under the Plant Quarantine Act, however, the government still permit the public and private institute to conduct the research and development of GM plant in the experimental field due to the uncertainty of the GM products for the public safety and health reason.

convention both 1978 and 1991 which are distinctive, uniformity, and stable[353]. Section 13 of the Act has given several exceptions including the registration of new plant varieties if the new plant variety has any adverse impact to the environment, health or public welfare354. For public safety, this legislation also empower the Minister to prohibit the production, sale distribution, importation, exportation of new plant varieties in order to prevent the diseases, the promotion of health, maintain public welfare, preservation and conservation of environment and biological diversity[355].

For the use of local domestic plant varieties, the Act has defined the local domestic plant varieties as a plant variety which exists only in a particular locality within the Kingdom and has never been registered as a new plant variety and which is registered as a local domestic plant variety under this Act[356]. The Act has provided that anyone who wants to use local domestic plant for any reasons must obtain permission from the local government organisation, farmers' group or co-operative in the name of the community to which the certificate of registration of the local domestic plant variety is granted, provided that approval of the Commission shall first be obtained[357]. For the benefit sharing agreement, the Act does establish the fund or

353 Thai PVP/ Section 11

354 Section 13. No registration under this Act shall be made of a new plant variety having a severely adverse impact, directly or indirectly, on environment, health or public welfare. A new plant variety derived from genetic modification may be registered as a new plant variety only upon a successful result of a safety appraisal with regard to environment, health or public welfare conducted by the Department of Agriculture or other agency or institution designated by the Commission, in accordance with the rules and procedure prescribed in the Ministerial Regulation.

355 Section 36. When necessity arises for the prevention of diseases, the promotion of health, the maintenance of public welfare, the preservation and conservation of environment and biological diversity or for other public interest, the Minister, with the approval of the Commission, has the power to issue a Notification prohibiting the production, sale, distribution in any manner, importation or exportation of new plant varieties for the period of time specified in the Notification. For the purposes of the national security, the maintenance of nutritious stability, the prevention of monopoly or for the purpose of other public interests, the Minister, with the approval of the Commission, has the power to issue a Notification authorizing general members of the public to do the acts specified in section 33 paragraph one, provided that appropriate remuneration shall be paid to the right holder of a new plant variety. Such Notification shall also specify therein the term of the authorization and the rates of remuneration. If, after action has been taken under paragraph two, it appears that the circumstance under paragraph two cannot be effectively prevented or alleviated, the Minister, with the approval of the Commission, may revoke the certificate of registration of that new plant variety.

356 Thai PVP Act/ Section 3

357 Section 48 A person, who collects, procures or gathers a local domestic plant variety or any part thereof for the purposes of variety development, education, experiment or research for commercial interest shall make a profit-sharing agreement in relation to the profits derived from the use of such local domestic plant variety. In authorizing any person to carry out the act under paragraph one and in making the profit-sharing agreement, the local government organization, farmers' group or co-operative to

so called Plant Varieties Protection Fund. The objectives of the Fund are to assisting and subsidising activities related to the plant varieties conservation, research and development[358] as can be seen in section 52[359]. Therefore, Thai PVPs have provided adequate intellectual property protection for the use of Thai domestic plant, protected plants and wild plant varieties for commercial purposes in Thailand. However, it should be noted that nowadays, Thai government has not finished listing and categorized the lists of plant varieties including the domestic plant and wild plant varieties in which the Thai authorities still cannot use it as a reference for the conditions of PIC and BS prescribed in the Thai PVP.

8.2.4: Does Thai legal system provide any room for the relevant laws to be re-interpreted in a way that can deal with the problem of bio-prospecting?

As can be seen from the prior section, Thailand does have legislation such as the Plant Act, Wild life Protection Act, National Forest Act, and the Forest Act which are very useful to control the use of biological resources found in Thailand. However, those legislations are separately put and used in different objectives such as illegal trafficking for the wild life animal or wild life plant in which this thesis sees that they have not been used for the protection of the bio-prospecting problem. Therefore, there is a question whether Thai lawyer or Thai judge can start to reinterpret the use of these legislations along with the protection of bio-prospecting problem from patent law. This can be asked whether the legal system in Thailand provides any room for the lawyer to bring the bio-prospecting reason to the court and tell the Court that the product or process cannot receive any intellectual property protection because the biological materials for the production of product or process fails to receive a proper permission. So the question is would the Central Intellectual Property and

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which the certificate of registration of the local domestic plant variety is granted shall make the agreement in the name of the community, provided that approval of the Commission shall first be obtained.

358 Thai PVP/ Section 54 and 55

359 Section 52 of the Thai PVP Act: A person who collects, procures or gathers general domestic plant varieties, wild plant varieties or any part of such plant varieties for the purposes of variety development, education, experiment or research for commercial interest shall obtain permission from the competent official and make a profit-sharing agreement under which the income accruing therefore shall be remitted to the Plant Varieties Protection Fund in accordance with the rules, procedure and conditions prescribed in the Ministerial Regulation.

International Trade Court (CIPITC) look at the Patent law and the Plant Act or Wild Life Act together when deciding the bio-prospecting case.

It is beyond the scope of this thesis to determine how the judge will interpret the law. However, it should be noted that Thai legal system was founded in the concept of civil law system; therefore the CIPITC would tend to follow the language prescribed in the legislation. The influence of court interpretation can only be seen from the Supreme Court, however, the interpretation of the Supreme Court still follows the language prescribes in the law. Therefore, for the question whether the court would interpret the patent law differently from what has been written in the Patent Act or consider other legislations when there is a dispute, the answer would presumably be negative because first the CIPITC would only look whether the product/ process meet the criteria of patentability and second the CIPITC would not look at how the raw material has been obtained since there is no requirement to do so as neither prescribed in the law. For the question whether the patent office would require additional criteria such as the PIC and BS on the issue of bio-prospecting before granting the patent protection, the answer would also be negative since the PIC and BS is not prescribed in the Thai Patent Act, therefore, they will not be part of the criteria of patentability and it will not be considered as criteria of patentability. As a consequence, the patent office will grant a patent protection to the product and process as long as the product or process meets the criteria of patentability as prescribed in the law. It should be noted, as of today, there is no court decision both at the CIPITC and at the Supreme Court deciding on the case of intellectual property protection and bio-prospecting issue[360].

8 3: How the recommended conditions and tool could be introduced in the Thailand's biodiversity legislation.

It seems to be that the Thai Plant Varieties Act provides the most adequate intellectual protection in which balance the interest of both the innovator through the exclusive rights for 20 years and the owner of natural resources by providing the conditions of BS and PIC. However, as can seen from the previous sections that

360 The Central Intellectual Property and International trade Court, www.cipitc.or.th (22 March 2009)

biological resources and the use of biotechnology does not limit only to the plant but it also includes animal, micro-biology and etc in which Thailand has not had adequate or amend the legislation that can properly deal with this problem. Since the law does not give any adequate support for the problem of bio-prospecting, therefore, this thesis finds that there are three options to deal with the issue of bio-prospecting under the intellectual property protection scheme in Thailand.

The first option is to add the additional criteria of patentability which are the BS, PIC and SIA as recommended in the chapter 5 and 6. However, as mentioned, this option will dangerously violate and inconformity to the TRIPs agreement.

The second option is to amend the law by adding section with regards to bio-prospecting issue in the Patent Act. In this section, the Patent Act does not need to give any details on the bio-prospecting issue in the Act but it could be amended by saying that the grant of patentability invention shall be complied with the other Act. In this case, Thailand might need to enact a new legislation such as the Biological Diversity Act which covers the issues of bio-prospecting including the intellectual property protection of product or process arising out of the use of the biological resources, the access and use of the biological resources, the protection of biological diversity according to the geographical and legally-defined boundaries, and etc. It should be said that there are four main objective of writing a new Act. The first objective is to be able to control, manage, and administrative the use and access of the biological resources in Thailand in order to protect the sovereign rights and interest of the country by combining and revising the Acts those relate to the biological resources which have been supervised through different governmental agencies (since one of the main problems of the use and control of natural resources in Thailand is the problem of enforcement.) The second objective is to give flexibility for the policy maker to amend the law or issue the administrative guidance on the issue of the use of biological resources in Thailand as the time goes by. The third objective is to give flexibility for the country to write a new law which does not need to comply with any single international agreement but to comprise of different objectives of many international agreements with regards to the use and benefit arising out of the biological diversity and resources such as TRIPs, CBD, CITES, ITPGR, UN Declaration on Human Rights, and etc into one single Act. Lastly, for the country where it was found upon the concept of a civil law system like Thailand, the new

legislation will give the court a guidance to interpret the law in such a way that look at the intellectual property scheme not only from the innovator point of view but also from the different issues under the intellectual protection scheme through different legislation.

The third option would be to amend the Patent Act by adding additional section with regards to bio-prospecting; however, the content of the Act will be different from the second option. This option is to be made if Thailand decides not to enact a new law as recommended in the second option. In this section, the patent law shall stipulate that the illegal raw material obtained for the production of product or process, such product or process shall not be granted the intellectual property protection. This option might be the option that gives a logical explanation in a sense that stolen property shall not be used as a raw material for the grant of patentability protection. In this case, Thailand can use the existing legislations to protect the use of her biological materials without permission since it seems to be that Thailand has enacted well written legislations those protect wild life and plants according to the geographical and legally-defined boundaries and the regulation on the access and use of biological resources.

However, the main problem that Thailand is facing is Thailand must urgently list all her biological materials in order to be able to identify the biological materials those are protected. It should be noted here that the benefit arising out of the legal amendment will shift the prospectus of the use of biological resources in Thailand. The owner of the natural resources will directly benefit to the use of it from the royalty fee, however, it should be noted that the change can result to the increase in price of the product and legal disputes.

From the above options, the second option appears to be the most suitable option for Thailand in order to deal with the problem of bio-prospecting because the new legislation should be able to deal with all the problems regarding to the biological resources and to protect and use the biological resources in Thailand sustainably.

8.3.1: How the Thai Biological Diversity Legislation should be written

Thailand has many laws that can control the use of natural resources such as plant varieties, animal, geographical and legally defined boundaries' legislation and

etc; however, those legislations were enacted for different objectives in which they have been using for different purposes by different departments and ministries. As consequences, the problem of bio-prospecting in Thailand has never been properly addressed especially when it comes to patent protection on biological product or process with regards to the problem of bio-prospecting. In the previous section, there were three options available in order to address the problem of bio-prospecting. It was argued that it would be better if the Thai government chose the second option by enacting a new legislation that is comprehensively reached a state of acceptance and providing a clause in the patent law as suggested. This section therefore analyzes how biodiversity legislation could be used as a tool to deal with the problem of bio-prospecting.

There are four main parts that are necessarily worth examining in order to ensure that the bio-diversity legislation that can be recommended for Thailand will give it the power to deal with the problem of bio-prospecting. They are as follows:

8.3.1.1 Objective

For the biodiversity legislation, the objective should be written to cope with as many problems as the lawmaker would like to address with regards to biological resources. Therefore, it is up to Thailand whether they would like to see the biological legislation serve with different objectives or a single objective like the India Biodiversity Bill. For example, the Biological Diversity Legislation of South Africa has comprised of many objectives[361], therefore it was divided into different sections[362] to serve each objectives, whereas, in some legislation such as the India Biodiversity Bill, it was intentionally and specifically written for the problem of bio-

361 The objectives of this Act are-(a) within the framework of the National Environmental Management Act, to provide for-(i) the management and conservation of biological diversity within the Republic and of the components of such biological diversity (ii) the use of indigenous biological resources in a sustainable manner; and iii) the fair and equitable sharing among stakeholders of benefits arising (b) to give effect to‘ ratified international agreements relating to biodiversity which are binding on the Republic (c) to provide for co-operative governance in biodiversity management and conservation (d) to provide for a South African National Biodiversity Institute to assist in achieving the of this Act.

362 Such as in the chapter 4 stipulated about Threatened or protected ecosystems and species, chapter 5 stipulated about species and organisms posing potential threats to biodiversity, chapter 6 stipulated about bio-prospecting, access and benefit sharing, chapter 7 stipulated about permit, and etc.

prospecting. However, this thesis finds that one of the objectives of the biodiversity legislation with regards to bio-prospecting problem Thailand should be written is to preserve and manage the use of biological resources in a sustainable way and to provide for a fair and equitable sharing in benefits arising from the utilization of bio-prospecting for biological resources in Thailand.

8.3.1.2 Formal Conditions/ Tool:

Two conditions and one tool were examined in previous chapters that could ensure that the biological diversity legislation will be effectively implemented. Those conditions and tool are the Prior informed Consent (PIC), the benefit sharing (BS) and the Social Impact Assessment (SIA). However, as discussed in chapter 4, there are different ways these conditions can be implemented. Therefore, further analysis is needed to examine how these conditions would be best to serve Thailand, as follows:

8.3.1.3 Prior Informed Consent (PIC)

The main objective of the PIC is to recognize the sovereignty of state over her natural resources. Bio-prospectors who would like to take out the biological resources must receive a permit[363] from the authority concerned. In order to ensure that the PIC will reflect the need of every stakeholders, then, there are different ways in which the lawmaker can decide who shall have the authority to grant an access of biological resources through the permitting system. The first one is that the PIC consent and approval shall come from the competent authority. The second one is

363 It should be noted that permitting system that this thesis would like to introduce will be decided by the communities or authorities concerned, however, the person bio-prospector would require a permit to be able to exploit the biological resources. It should also be noted that permitting system that this thesis would like to introduce will be different than the other system. This mean that the Permitting system in this case would not go for an expensive to order to receive a concession or monopoly right over the property. This means that it will not be sold at an expensive price because this thesis is afraid of excluding regular people or indigenous people who has a knowledge with lack with abundant financial assistance compare with corporation or scientist who receive a big research and development funding. So therefore, the price of bio-prospecting will be largely considered when the benefit sharing agreement is negotiated with the authorities concerned. The SIA can be used as a tool to quantify and qualify the permitting system and benefit arrangement. For the public land, it should not be a problem because the authority concerned has legal boundary to control and access the area according to the law. However, for the private area, this problem can be solved by the used of National Information System Unit (NISU) as recommended in Chapter 8: 8.3.1.4.1 in order to qualify the property benefits and they can put in practice through a permitting system.

that the PIC consent shall come from community who own the natural resources but the approval of the consent given by the community shall come from the authority concerned. The last one is that both the PIC consent and approval shall come directly from the community, however, the competent authority is still act as a official agent who examine that the consent and approval are legally obtained before giving a permit. For Thailand, this thesis sees that the second option would be the most suitable one for Thailand because it is justified for the community who own the biological resources to have the right to decide on the use of their resources, however, the state should still act as an authority to ensure that the consent is given in a justifiably manner. However, it should be noted that the second option would be best served when the law of the country has been designed to ensure that the community will be represented by an agent or any person acting on behalf of them who can officially, legally, transparently, and accountably represent them because if the law does not provide anyone who can act for them then the decision making process of the PIC could easily be jeopardized[364]. For the other options, the first option can still be considered as a good option because the state or the authority concerned who has wider expertise in this area can decide what would be the best interest for the community, however, this thesis still believe that the community should also have to right to decide when it comes to the implication of utilizing their resources. After all, the first option can still be considered as a provisional option for the country where concern with the bio-prospecting problem but the law has not designed to decentralize the power between national and local. For the third option, even though this option can really represent the need of the community because the community will be the

364 There is an evidence of the recognition of the rights of indigenous people as can be seen in the Draft United Nations Declaration on the rights of indigenous peoples 1994. For the draft UN Declaration on the rights of indigenous people, even thought his declaration has not been adopted but the essence of the declaration which recognized the prior informed consent concept and the rights of people to their natural resources and traditional practices as can be seen as follows: Article 29: Indigenous peoples are entitled to the recognition of the full ownership, control and protection of their cultural and intellectual property. They have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs and visual and performing arts. Article 30: Indigenous peoples have the right to determine and develop priorities and strategies for the development or use of their lands, territories and other resources, including the right to require that States obtain their free and informed consent prior tot the approval of any project affecting their lands, territories and other resources, particularly in connection with the development, utilization or exploitation of mineral, water, or other resources. Pursuant to agreement with the indigenous people concerned, just and fair compensation shall be provided for any such activities and measure taken to mitigate adverse environmental, economic, social, cultural, or spiritual impact.

one who give the consent and approval of the use of their natural resources; however, there is no assurance in this option that the decision of the community will really represent the community's need because there is no mechanism or any official agent that can filter the community decision and therefore, there will then be a question of how can it be assured that the decision made by the community can be accountable, transparent, and will not be permanently dominated by a particular group of people in the community.

8.3.1.4 Benefit sharing (BS)

In order to ensure that the BS will come out from every stakeholder, then, there are different ways in which the lawmaker can decide who shall have the authority to decide the benefit arising out of the utilization and access of biological resources. There are three options of BS can be chosen. The first option is that the BS decision can be agreed between the bio-prospector and the competent authority. The second option is that the BS decision can be privately agreed between the bio-prospector and the owner of biological resources/ community however, the approval of BS agreement still needs to go to the competent authority. For the third option, it will be dealt privately between the bio-prospector and the owner of the biological resources. The second option could consider to be the most suitable option for Thailand because the community who own the biological resources shall have the right to decide on the benefit arising of the utilization of their resources, however, in order to ensure that the BS agreement is optimally benefit both for the community and the country, therefore, the competent authority is still necessarily important to involve in this matter in the final process of approval. For the first option, this thesis is of the similar opinion to the first option of the PIC because in many countries, withholding the power at the state/ national level to decide on the BS might be better than giving it to the community where the law of the country has not been designed to decentralize the state power to the community. Therefore, it is better to have the competent authority that can represent the community to decide the appropriate amount of the BS that the community should receive. For the third option, this thesis is also of the opinion similar to the third option of the PIC because there is no guarantee the benefit arising out of utilization of biological resources will really represent the need

of the community because the community will be the one who give the consent and approval of the use of their natural resources; however, there is no assurance in this option that the decision of the community will really represent the community's need because there is no mechanism or any official agent that can filter the community decision and therefore, there will then be a question of how can it be assured that the decision made by the community can be accountable, transparent, and will not be permanently dominated by a particular group of people in the community.

8.3.1.4.1 The Justifications of BS between the communities

There have been a lot of criticisms of how the BS can be justifiably determined between the communities when one community receives a benefit sharing while the others who live nearby would not. As consequence, one community will have extra money to spend on things that the law allows the money to be used for whereas the other communities cannot. The community who own the biological resources might see that they should be entitled as a sole owner of biological resources to receive benefits sharing arising out of the utilization of biological resources. This thesis agree that the owner of the biological resources shall legally receive a benefit sharing however it would not be fair especially when the community where is not far apart would be financially differentiated because they don't have any valuable biological resources. This can be seen that the benefit sharing scheme might not be optimally implemented as designed for because it causes the differences among the communities financially and socially, therefore, this thesis would like to recommend an approach to diminish the size of the gap.

As can be seen from the above paragraph, there are two questions need to be addressed in order to answer the above problem. Those are the question of who own the biological resources and the issue of how the BS can also be shared with the other communities who do not own the valuable biological resources.

Firstly, the issue of ownership of biological resources is important because it can necessarily be used to identify the owner of the biological resources before the benefit sharing is to be determined and agreed. Even though, the ownership is the most appropriate basis for PIC and BS but is not sufficient in itself because it is a good method of dealing with the first stage of assigning rights and calculating

benefits, but there should also be another process of ensuring that sharing of benefits is much wider in the general community. Therefore, it is necessarily important to firstly address how we can we assure the grant of ownership of biological resources is fairly determined. This thesis believes that in order to address this question, there shall be a National Information System Unit (NISU)[365] under the supervision of the national competent authority to enlist all the valuable biological resources biological resources, their by-products, innovations and practices associated with their use and applications and knowledge and the traditional use of biological resources in order to serve as prima facie evidence of ownership of the resources; to serve as evidence of prior art, which might be used to challenge patent applications; and to protect traditional knowledge, innovations or practices against continuing erosion and promote their revitalization. In order to do so, there are three ways of the lists of the valuable biological resources can be collected. The first one would be the national competent authority will establish its own internal agency to survey and list all biological resources and practices and pinpoint where it can be found. The second one would be the local authority such as the TAO will give a formal notification to the National Information System Unit of the valuable biological resources and practices those can be found in the area. The third one would be the bio-prospector can inform the NISU of the valuable biological resources and where they can find them. As consequences, the national competent authority can acquire the information of the biological resources and the practice of the use of biological resources as a database. In order to bring into a definite end of who would be entitled to own the biological resources and practice, the competent authority will need to set up an ad hoc committee to determine the criterion of ownership and scientifically decide who would be the owner of the biological resources and the practice of the use of such resources. Therefore, at this stage, the process of identifying the ownership of the resources and practices will be fairly, scientifically, and justifiably determined.

Secondly, there is a question of how to bridge the differences between the communities with regards to the benefit sharing issue. There are two assumptions that

365 The recommendation of establishing a National Information System can be seen in the article 64 of African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the regulation of access to biological resources.

this thesis sees it is necessary to hold as an opinion. First, the owner of the biological resources shall legally receive the benefit sharing arising out of the utilization of resources and give the PIC on the utilization of biological resources and its practices based on the two-tier system. Secondly, even though the community near by or far away is not the owner of biological resources as determined by above process but they should not be totally left out of the bio-prospecting regime because there will be a differentiation between the communities. Therefore, this thesis would like to recommend that the national competent authority shall establish the Bio-prospecting Trust Fund as a National Fund which will be allocated to or requested by the communities though out the country as a national fund. The objective of the Fund can be set and used for, for example, the management and conservation of heritage sites and biological diversity or compensating or rehabilitating and socio-economic development of areas from and apart from where such biological resources or knowledge associated. The percentage of money obtained for the trust fund which from the benefit sharing arising out of the utilization of resources shall be determined on the case by case basis or can be specified in the legislation[366] depends on how the lawmaker would like it to be. For the allocation of the fund to the communities, it shall be determined on the case by the case basis depends upon the types of the activities, plans, or programs with regards to bio-prospecting issues as it will be determined by a special committee set up by the National Competent Authority. The example of the trust fund can be seen in the article 85 of the Biodiversity Act of Africa in which establishment of bio-prospecting Trust fund will receive all moneys arising from benefit-sharing agreements and material transfer agreements, and due to stakeholders must be paid, and from which all payments to, or for the benefit of, stakeholders must be made. In addition, the National Government can also contribute the money to this fund in order to use in the business of National Biodiversity Authority, or to keep any grants or charges by the National Biodiversity

366 The specification of the money that go to the trust fund can be seen in the article 8 of Peru act as follows: Percentage accruing to the Fund for the Development of Indigenous People: A percentage which shall not be less than ten per cent of the value, before tax, of the gross sales resulting from the marketing of goods developed on the basis of collective knowledge shall be set aside for the Fund of the Development of Indigenous Peoples provided for in Articles 37 et seq. The parties may agree on a greater percentage according to the degree of direct use or incorporation of the said knowledge in the resulting end product and the degree to which the said knowledge contributed to the reduction of the cost of research and development work on derived products, among other things.

Authority in order serve the objective of Biodiversity Legislation. This could be learnt from the example of India Biodiversity Act[367] which gives the money from the Fund for different purposes such as the conservation of biological resources and development of areas from where such biological resources or knowledge associated has been accessed or socio-economic development of areas referred to in consultation with the local bodies concerned.

In the conclusion, the above paragraphs have explained how to address the problem which might arise from the benefit sharing scheme. The process of determining of ownership is necessarily important to identify who should be entitled to receive the BS and the establishment of the Fund is important because it will be allocated as a program or activity which will promote the sustainability use of biological resources throughout the country.

8.3.1.5 The Competent Authority/ies

This section will explain why this thesis is of the opinion that the second option of both the PIC and BS would be the most suitable option for Thailand. This part will illustrate that Thai Law has been designed to decentralize the power between the state and local community. In addition, it will also show who would be the best agent at the local level and the national level to decide about the PIC and BS scheme. This thesis is of the opinion that at the community level, the Tambon Administrative Organization (TAO is equivalent to Sub-district Administrative Organization) can act as an official agent for the community for the PIC and BS decision and for the national level, it would be the Office of Natural Resources and Environmental Policy and Planning under the Ministry of natural Resources and Environment.

This can be explained when Thailand has enacted the TAO Act B.E. 2537 (1994) which established the Tambon Administrative Organization (Sub-district

367 Article 27: Application of National Biodiversity Fund. 27. (1) There shall be constituted a Fund to be called the National Biodiversity Fund and there shall be credited thereto--a) any grants and loans made to the National Biodiversity Authority under section 26, 15 (b) all charges and royalties received by the National Biodiversity Authority under (his Act; and (c) all sums received by the National Biodiversity Authority from such other sources as may be decided upon by the Central Government. (2) The Fund shall be applied for- (a) channelling benefits to the benefit claimers; (b) conservation of biological resources and development of areas from where such biological resources or knowledge associated thereto has been accessed; (c) socio-economic development of areas referred to in clause (b) in consultation with the local bodies concerned.

Administrative Organization) in order to implement the decentralization policy and to take a step forward in a realization of a village self management policy[368]. There are two lines of work for TAO; the first one is to coordinate and to carry out plans and projects designed by government agencies and the second one is to carry out eight obligatory functions and four optional items of work including to protect and to preserve of the environment and natural resources in their jurisdictions. The TAO is composed of two elected representatives from each village in a *tambon* (sub-district). In the TAO itself, it is divided into two parts which are the council comprised of all elected member and the executive part which is composed of three member of the elected out of and by the TAO members[369]. For the TAO's revenue, there are multiple routes of TAO's revenue as can be divided into three categories as follows: taxes and fees, state support budget, and TAO income. For the taxes and fees, they can come from taxes of the land, building, sign board, duties from charges, surcharges, fees, fines, licenses, permits, Value added tax such as slaughterhouse licenses, gambling licenses, special business taxes, liquor taxes, excise taxes, automobile/ vehicle registration taxes. For the TAO income, it can come from TAO own properties, provision of infrastructure facilities and services, donations, and etc. Therefore, the TAO can be seen as a decision maker at the community level to give the consent on the PIC and BS on behalf of the community with regards to the bio-prospecting.

For the state's competent authority, it is of the opinion that the Thai government has already had the competent authority who can serve both as a competent authority that monitor the legislation and is in charge of approving the PIC and BS agreement. According to the new government restructuring program, the Office of Natural Resources and Environmental Policy and Planning (ONEP) under the Ministry of Natural Resources and Environment which serves as the national focal point for Convention on Biological Diversity (CBD) and servers as the National Biodiversity Reference Unit (NBRU) to ASEAN Regional Centre for Biodiversity Conservation (ARCBC) has the responsibility to formulate policies and integrated plans, propose the measures on administration and management of natural resources

368 Chaiyan Rajchagool, Tambon Administrative Organization: Are the People in the Dramatis Personae or in the audience?

369 However, the provincial governor still direct and oversee the operation of TAO in order to ensure that it functions within the framework of law and rules laid down by the legislations

and environment and coordinate to transform them into practice in order to integrate system of an administration and management of natural resources and environment, based upon area, function and participation principle, to promote the balance between utilization and preservation, rehabilitation and conservation of natural resources, as well as effective coordination on utilization for sustainable development with acceptable environmental impacts, and to strengthen capability of local government to administrate and manage natural resources and environment[370] could be served as a competent agency to monitor the implementation of the legislation, the PIC, and BS through the establishment of the national board who will have a duty to approve the PIC and BS. As previously mentioned in the previous chapter that the board should be comprised of different groups of people both the government officials, academic, expert, renowned non-governmental groups, representative of the public organization, local community because the board can give different perspectives when the biodiversity law is implemented and especially when it comes to decision of granting or approving a permit to access or on the benefit sharing agreement.

Therefore, it can be seen that Thailand has readily furnished with the agencies who can act as an agent to decide about the PIC and BS for the protection of bio-prospecting problem both locally and nationally. However, the TAO Act still need to be amended on the details of how the TAO can be effectively and efficiently performed with regards to the bio-prospecting problem such as the establishment of an independent committee on bio-prospecting, how the BS can be utilized, and etc in order to give an efficient operation of their duties.

8.3.1.2 Social Impact Assessment

With regards to SIA, this thesis is of the opinion that the Social Impact Assessment could be used both, as explained in the chapter 4, as a tool to justify BS scheme and a tool to justify access and use of biological resources. Even though SIA has not been widely used in Thailand but the acceptance of the other assessment method has been officially visualized as can be seen from the acceptance of the

370 These responsibilities have been excerpted from the Ministerial Regulation "Ministerial Subordinates of the Office of Natural Resources and Environmental Policy and Planning, Ministry of Natural Resources and Environment in B.E. 2545 (2002)

Environmental Impact Assessment[371] as an official assessment for the environmental protection. Therefore, if SIA can be put into the legislation as an official tool to assess the grant of an access or use of biological resources as EIA and to assess the BS decision, then SIA would both qualitatively and quantitatively be able to assure the community and the competent authority to mutually agree with the result academically and by using reason in an orderly cogent fashion.

8.4. Conclusion

In the conclusion, this chapter has explained who should decide for the PIC and the BS scheme and how the biological diversity legislation could be effectively designed for Thailand. It is argued that the second option of the BS and PIC with readymade agencies both locally and nationally will ensure that the bio-prospecting problem will be effectively and efficiency reach the state of acceptance. However, it is unavoidably important for the lawmaker to require SIA as a method to justify the decision both at the community and at the national level. In addition, in order to increase the efficiency and effectiveness of the biodiversity legislation, the revision of the patent law is required with regards to the legitimacy of the acquiring the raw materials.

More specifically, this thesis would like to recommend that in order to make the biological legislation effectively and efficiently implemented the intellectual property legislations such as the Thai Patent law B.E. 2522 needs to be revised. The revision needs not to be put any special conditions for the problem of bio-prospecting but the law should be re-written about the legitimately of how the biological resources has

371 The first mandatory provision of the EIA was issued in 1981 Under Sec 46 of the Enhancement and Conservation of Nation of National Environmental Quality Act 1992. The Ministry of Science, Technology, and Environment with the approval of National Environment Board (NEB) has the power to specify by notification the type and size of projects or activities requiring EIA. (Nowadays, the responsibility of the EIA goes to the Office of Natural Resources and Environmental Policy and Planning (ONEP) under the Ministry of Natural Resources and Environment) EIA has to be prepared by a consulting firm which is registered by OEPP and has to be submitted to OEPP for preliminary review before final decision on the report will be made by the Expert Review Committee. Environmental Impact Evaluation Division (EIED) of OEPP will be responsible for examine the environment impact assessment report and related documents filed there with and also the preliminary review. The report together with the preliminary comments will then be proposed to the Expert Review Committee for final consideration. Therefore, the SIA can be introduced through the acceptance as the EIAs.

been acquired as can be seen in the Egyptian Law on the Protection of Intellectual Property Rights as follows[372]:

> Where the invention involves biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage, the inventor should have acquired the sources in a legitimate manner.

Therefore, any patent applicant who applies for the patent protection must be aware of the legitimately of biological resources for the product or the process whether it is legally obtained. In addition, this revision might be able to ensure that the product/ process from aboard which apply for the patent protection needs to prove to the authority concerned that they have legally and legitimately acquired. However, the developed counties might rebut that the above requirement might violate the non-discrimination based on fields of technology because the above paragraph was written particular for the biological products; therefore, this thesis is of the opinion that the sentence can be revised as follows:

> "The raw material of product, process, or product by the process in all fields of technology shall acquire the sources in a legitimate manner"

Although much of the analysis above is concerned with Thailand and its authority structures, the same arguments of using PIC and BS, providing for public participation and consulting proper stakeholders, and SIA as a tool would apply to any developing country that faces problem of bio-prospecting. Similar structures could be used. Also the use and content of biodiversity legislation suggested here could draw some lessons for other developing countries because it gives legal powers to assert State sovereignty and links with patentability. Therefore, this analysis also applies to other developing countries with abundant biodiversity.

372 Law on the Protection of Intellectual Property Rights of Egypt / Art 13

Chapter 9: Summary

The bio-prospecting problem arises from controversies surrounding the new global of intellectual property rights scheme[373] and the differences of the understanding the importance and the implication of the TRIPs agreement between the North and the South. The issue of bio-prospecting should not have been a problem if the natural resources were still considered to be "free for all, belong to none" and there was no intellectual property protection over the product and process derived of the biological resources. The problem of bio-prospecting has been seen as an arisen of the consequence of a change of political context of the sovereign rights over the natural resources, development of technology, and the introduction of intellectual property protection over biological resources.

It should be noted that bio-prospecting is good for the development of a new product and process, however, there are also some adverse affect of bio-prospecting as well. For example, first, when there is an introduction of a new product and process developed from bio-prospecting in developing nations where they have different socio-economic background, then there have been numerous criticisms about its implication of products/ processes especially the bio-tech products to the economic, social, environment, and etc of the developing nations. Secondly, since the concept of sovereign right over natural resources has been shifted and the introduction of patent law over biological resources, the word "bio-piracy" was introduced as a term that express the concerns of developing nations over their natural resources in particular biological resources that might have been taken without their consent.

Developing nations have found that it is their right to protect their biological resources for their own interest; however, there is no legal mechanism to ensure that bio-prospecting activities especially from the North will not get back to them in a negative consequence as a product or process and their biological resources will not be grants a patent protection before it has been applied for the product and process. Economically speaking, nowadays, the market value of products and processes

373 Peter Drahos and Ruth Mayne, Global Intellectual Property Rights Knowledge, Access, and Development, 2002 preface Thai PVP/p. 10

derived from the biological products has been estimated billions of dollars[374]. Therefore, it is economically viable and reasonable for the inventor, investor, and policy maker both in the developed and developing nations to give their concerns over the problem of bio-prospecting.

The thesis has explained the law, in this case would be patent law, makes the biological resources patentable with an enhancement of TRIPs agreement which make it globally accepted. Looking from the country where they have abundant natural resources' point of views, the criteria of patentability under the TRIPs agreement does not recognize the sovereign rights of the countries over the natural resources as similar to the Convention of Biological Diversity and does not provide any safeguard mechanisms from bio-prospecting activities before granting monopoly rights over the products and process[375]. Therefore, many stakeholders in developing nations criticize the appropriateness of TRIPs, particularly whether patent law over the biological resources is justified and whether it should be amended. It should be noted that developed nations who directly benefit from the patent law will, as mentioned, never want to amend the articles in the TRIPs agreement whereas the developing nations would like to see TRIPs to balance the right of the innovator and the owner of biological resources. This evidence can be seen from the long process of discussion and countries' position regarding the problem of bio-prospecting at the TRIPs Council.

The purpose of this thesis was to find out how the problem of bio-prospecting should be dealt with in order to balance the right between the right of innovator who should be rewarded for his effort and ingenuity and the right of owner of biological resources who legitimately should have at least a say and enjoy the benefit arising out of his or her biological resources. In addition, this thesis has given example of Thailand as a case study with the reasons that Thailand has abundant biological resources and has not legally equipped herself with conditions and tools for the problem of bio-prospecting.

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374 Department for International Development, BIOPROSPECTING PROJECT, "http://www.odi.org.uk/tropics/projects/3308.htm" (25 September 2005)

375 Agreement on Trade Related Aspects of Intellectual Property Rights/ / Art 27:1 "Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve and inventive step, and are capable of industrial application.

This thesis started with the literature review in order to give a picture of how the problem of bio-prospecting has been discussed globally. In the literature review, it has shown that there are many discussions in issues related to the problem of bio-prospecting. There have been discussions both pro and con regarding grant of patent protection over the biological resources, bio-prospecting and sovereign rights of states over biological resources, mechanisms which are PIC and BS. Then, the chapter moves on with an explanation of how the patent law is developed and interpreted in Europe and the US in order to give a background for a reader to understand the patent law and its interpretation in two key jurisdictions in chapter 3. This thesis sees that the interpretation of patent law has only been interpreted in favour for the expansion of the process of technological development and the growth of the technological industry and there were a lot of literatures disagreeing with the intellectual property schemes and have recommended to stop developing biotechnology or abandon the protection of intellectual creation on biological resources. With regards to the problem of bio-prospecting, this thesis has made argument that the lawmaker can look at how the patent law should still be developed for the expansion of technological and guarantee of the investor's return but at the same time it also needs to recognize the sovereign of state over her biological resources under the principle of international law which has been practiced for centuries.

This thesis has then moved to analyse TRIPs agreement and explain of how TRIPs agreement has been written and interpreted with regards to the problem of bio-prospecting in chapter 4. This thesis has also strengthened the importance of enforcement mechanism and analyze whether the reinterpretation or amendment of TRIPs agreement is feasible to address the problem of bio-prospecting. This thesis found out that TRIPs articles is very rigid and have been a problem for the problem of bio-prospecting in the past few years. The thesis found that there are two options to deal with the problem of bio-prospecting under the TRIPs agreement. The first option is to find exceptions from the articles of the TRIPs agreement and second option is to amend the TRIPs agreement. This thesis would like to conclude that the amendment option is a very good option because it directly addresses the problem of bio-prospecting but the problem of this option is it is difficult to get a consensus at the council since there are still a lot of disagreements between the members of the TRIPs

Council of how to address the problem of bio-prospecting as can be seen from the second section of the chapter 4. In order to use this option, this thesis has proposed that Articles 7, 8, and 27.2 could be used as a rationale to introduce a tool to deal with the problem of bio-prospecting without touching the articles of the TRIPs agreement.

This thesis moved on that when the TRIPs has been interpreted, then the mechanisms or tools or conditions are needed to be introduced in order to be able to counter the problem of bio-prospecting in chapter 5. These formal conditions are Prior Informed Consent (PIC) and Benefit Sharing Schemes (BS). These two conditions will be able to help any countries to be able to control the access and use of biological resources because States have sovereign rights to introduce any conditions or tools to deal with the problem of bio-prospecting with the reinterpretation of the article 7, 8, and 27.2 of the TRIPs agreement.

The thesis has then moved on to introduce the concept of Social Impact Assessment (SIA) in chapter 6. SIA has been introduced to counter the problem of bio-prospecting to be as a tool to guide and justify decisions made by the parties concerned when the formal conditions are to be used. It is argued that it is necessary for the parties concerned to be equipped with a tool to rationalize their decision in a wider and complete picture of the consequence of permitting the use of biological resources and maximizing benefit arising out of utilization of biological resources. The thesis has explained what SIA is and how can we use it with the problem of bio-prospecting. This thesis has pointed out that SIA will help the decision maker to identify the benefit and cost when permitting the bio-prospecting activities and when the benefit sharing scheme is to be made. There are three options were given for the policy maker to choose which are, first, to put it as additional criteria of patentability, second, to put it as a tool of granting an access or use of biological resources, and third to use SIA as a justifier the BS scheme. At the end, this thesis has concluded that the second and the third options are likely to be chosen in order to address the problem of bio-prospecting because the first option will face with the political difficulties which may prevent the first option being used in practice.

Then the thesis moved to introduce Biological Legislation as a potential way of dealing with the problem of bio-prospecting without contravening with the TRIPs agreement in chapter 7. At the beginning, it reviews the use of biodiversity laws, how

biodiversity legislation has been written in different countries and regions in order to understand the strengths and weaknesses in different laws and draw lessons on how biodiversity legislation might be best used in Thailand.

It is argued here in this thesis that it would be in the best interest of the developing nations to put the conditions and tool in a separate legislation because of two important reasons. The first reason would be to escape the rigidly written clauses of the TRIPs agreement and the political difficulties of achieving change at the WTO. The second reason would be the new legislation can be written and enacted in order to control the access and the utilization of the biological resources in the country, therefore, it would be faster for the country to introduce, revise, and regulate the use of their biological resources before granting any intellectual property protection.

The next chapter will be a recommendation chapter. It will explain how the reinterpretation of TRIPs, tools and conditions can be dealt with the bio-prospecting problem in the context of Thailand, legally and systematically.

Chapter 10: Recommendations

In this chapter, it will explain of how the previous chapters could be put into place like Thailand. The reason Thailand was chosen in this thesis was Thailand is similar to many developing countries which contain abundant biological resources but lack legal expertise when they signed the Marrakech Agreement in 1994. Without being aware of the consequence of TRIPs, Thailand did not have any means to deal with the problem of bio-prospecting properly. It has therefore recommended that Thailand should choose to enact the new biological legislation as a way out for the problem of bio-prospecting. The new biological legislation will be equipped with the two conditions and one tool which are the Prior Informed Consent (PIC), Benefit Sharing Scheme (BS), and Social Impact Assessment (SIA) respectively. The Social Impact Assessment has been recommended as a tool to qualitatively and quantitatively rational the benefits and costs socially from permitting bio-prospecting (for PIC) and to assess and quantify the benefit arising out of granting of utilization of biological resources (for BS) before the bio-prospecting activity is to be granted.

As mentioned in the above paragraph that two ways of dealing with the problem of bio-prospecting under the TRIPs agreement have been discovered during this analysis. The first option would go for the amendment of the TRIPs agreement, however, as mentioned even though this option would directly address the problem of bio-prospecting but it is difficult to amend the TRIPs agreement because of differences between developed and developing nations as can be seen from the discussion at the TRIPs council. For the second and recommended option, enacting a new legislation or so called biological legislation would be the best solution in order to escape the rigidity of TRIPs articles as explained in Chapter 4 and would address the problem of bio-prospecting in the long. The thesis has finally concluded that biodiversity legislation needs to be equipped with conditions and tools to help the legislation to deal with the problem of bio-prospecting in Thailand effectively and efficiently. Those conditions and tool are the Prior Informed Consent (PIC), Benefit sharing (BS), and Social Impact Assessment (SIA).

This thesis has recommended that in the bio-diversity legislation for Thailand, it should be composed with four main parts as follows:

1. Objective

   This thesis has recommended the objectives of Bio-legislation should be to preserve and manage the use of biological resources in a sustainable way and to provide for a fair and equitable sharing in benefits arising from the utilization of bio-prospecting for biological resources in Thailand.

2. Formal Conditions/ Tool:

Two conditions and one tool were recommended. Those conditions and tool are the Prior informed Consent (PIC), the benefit sharing (BS) and the Social Impact Assessment (SIA). The details of why and how it should be best serve are as follows:

2.1 Prior Informed Consent (PIC)

The thesis has recommended, as mentioned in previous chapters, the bio-diversity legislation to equip with PIC. This thesis has explained of how the PIC will be used as it has been given with three choices. Those are as follows:

1. The first option is to add the additional criteria of patentability which are the BS, PIC and SIA as recommended in the chapter 5 and 6. However, as mentioned, this option will dangerously violate and inconformity to the TRIPs agreement and politically be difficult to amend it.
2. The second option is to amend the law by adding section with regards to bio-prospecting issue in the Patent Act. In the section, the Patent Act does not need to give any details on the bio-prospecting issue in the Act but it could be amended by saying that the grant of patentability invention shall be complied with the other Act. In this case, Thailand might need to enact a new legislation such as the Biological Diversity Act which covers the issues of bio-prospecting including the intellectual property protection of

product or process arising out of the use of the biological resources, the access and use of the biological resources, the protection of biological diversity according to the geographical and legally-defined boundaries, and etc.

3. The third option would be to amend the Patent Act by adding additional section with regards to bio-prospecting; however, the content of the Act will be different from the second option. This option is to be made if Thailand decides not to enact a new law as recommended in the second option. In this section, the patent law shall stipulate that the illegal raw material obtained for the production of product or process, such product or process shall not be granted the intellectual property protection. This option might be the option that gives a logical explanation in a sense that stolen property shall not be used as a raw material for the grant of patentability protection. In this case, Thailand can use the existing legislations to protect the use of her biological materials without permission since it seems to be that Thailand has enacted well written legislations those protect wild life and plants according to the geographical and legally-defined boundaries and the regulation on the access and use of biological resources.

This thesis has recommended the second options as the best way to escape the rigidity of TRIPs.

In addition, in order to ensure that the PIC will reflect the need of every stakeholder, then, there are different ways in which the lawmaker can decide who shall have the authority to grant an access of biological resources through the permitting system[376]. The first one is that the PIC consent and approval shall come

376 It should be noted that permitting system that this thesis would like to introduce will be decided by the communities or authorities concerned, however, the person who would like to bio-prospect would require a permit to be able to exploit the biological resources. It should also be noted that permitting system that this thesis would like to introduce will be different than the other system. This mean that the Permitting system in this case would not be expensive to order to receive a concession or monopoly right over the property This means that it will not be sold at an expensive price because this thesis is afraid of excluding regular people or indigenous people who has a knowledge with lack with abundant financial assistance compare with corporation or scientist who receive a big research and development funding. So therefore, the price of bio-prospecting will be

from the competent authority. The second one is that the PIC consent shall come from community who own the natural resources but the approval of the consent given by the community shall come from the authority concerned. The last one is that both the PIC consent and approval shall come directly from the community, however, the competent authority is still act as a official agent who examine that the consent and approval are legally obtained before giving a permit.

For Thailand, this thesis sees that the second option would be the most suitable one for Thailand because it is justified for the community who own the biological resources to have the right to decide on the use of their resources, however, the state should still act as an authority to ensure that the consent is given in a justifiably manner. However, it should be noted that the second option would be best served when the law of the country has been designed to ensure that the community will be represented by an agent or any person acting on behalf of them who can officially, legally, transparently, and accountably represent them because if the law does not provide anyone who can act for them then the decision making process of the PIC could easily be jeopardized[377]. For the other options, the first option can still be considered as a good option because the state or the authority concerned who has wider expertise in this area can decide what would be the best interest for the community, however, this thesis still believe that the community should also have to right to decide when it comes to the implication of utilizing their resources. After all,

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largely considered when the benefit sharing agreement is negotiated with the authorities concerned. The SIA can be used as a tool to quantify and qualify the permitting system and benefit arrangement. For the public land, it should not be a problem because the authority concerned has legal boundary to control and access the area according to the law. However, for the private area, this problem can be solved by the used of National Information System Unit (NISU) as recommended in Chapter 8: 8.3.1.4.1 in order to qualify the property benefits and they can put in practice through a permitting system.

377 There is an evidence of the recognition of the rights of indigenous people as can be seen in the Draft United Nations Declaration on the rights of indigenous peoples 1994. For the draft UN Declaration on the rights of indigenous people, even thought his declaration has not been adopted but the essence of the declaration which recognized the prior informed consent concept and the rights of people to their natural resources and traditional practices as can be seen as follows: Article 29: Indigenous peoples are entitled to the recognition of the full ownership, control and protection of their cultural and intellectual property. They have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs and visual and performing arts. Article 30: Indigenous peoples have the right to determine and develop priorities and strategies for the development or use of their lands, territories and other resources, including the right to require that States obtain their free and informed consent prior to the approval of any project affecting their lands, territories and other resources, particularly in connection with the development, utilization or exploitation of mineral, water, or other resources. Pursuant to agreement with the indigenous people concerned, just and fair compensation shall be provided for any such activities and measure taken to mitigate adverse environmental, economic, social, cultural, or spiritual impact.

the first option can still be considered as a provisional option for the country where concern with the bio-prospecting problem but the law has not designed to decentralize the power between national and local. For the third option, even though this option can really represent the need of the community because the community will be the one who give the consent and approval of the use of their natural resources; however, there is no assurance in this option that the decision of the community will really represent the community's need because there is no mechanism or any official agent that can filter the community decision and therefore, there will then be a question of how can it be assured that the decision made by the community can be accountable, transparent, and will not be permanently dominated by a particular group of people in the community.

However, this thesis has also recommended that Thailand must urgently list all her biological materials in order to be able to identify the biological materials those are protected. It should be noted here that the benefit arising out of the legal amendment will shift the prospectus of the use of biological resources in Thailand. The owner of the natural resources will directly benefit to the use of it from the royalty fee, however, it should be noted that the change can result to the increase in price of the product and legal disputes. This thesis has recommended that the second option appears to be the most suitable option for Thailand in order to deal with the problem of bio-prospecting because the new legislation should be able to deal with all the problems regarding to the biological resources and to protect and use the biological resources in Thailand sustainably.

2.2 Benefit sharing (BS)

In order to ensure that the BS will come out from every stakeholder, then, this thesis has recommended that there are different ways in which the lawmaker can decide who shall have the authority to decide the benefit arising out of the utilization and access of biological resources. There are three options of BS can be chosen. The first option is that the BS decision can be agreed between the bio-prospector and the competent authority. The second option is that the BS decision can be privately agreed between the bio-prospector and the owner of biological resources/ community

however, the approval of BS agreement still needs to go to the competent authority. For the third option, it will be dealt privately between the bio-prospector and the owner of the biological resources. The second option could consider to be the most suitable option for Thailand because the community who own the biological resources shall have the right to decide on the benefit arising of the utilization of their resources, however, in order to ensure that the BS agreement is optimally benefit both for the community and the country, therefore, the competent authority is still necessarily important to involve in this matter in the final process of approval. For the first option, this thesis is of the similar opinion to the first option of the PIC because in many countries, withholding the power at the state/ national level to decide on the BS might be better than giving it to the community where the law of the country has not been designed to decentralize the state power to the community. Therefore, it is better to have the competent authority that can represent the community to decide the appropriate amount of the BS that the community should receive. For the third option, this thesis is also of the opinion similar to the third option of the PIC because there is no guarantee the benefit arising out of utilization of biological resources will really represent the need of the community because the community will be the one who give the consent and approval of the use of their natural resources; however, there is no assurance in this option that the decision of the community will really represent the community's need because there is no mechanism or any official agent that can filter the community decision and therefore, there will then be a question of how can it be assured that the decision made by the community can be accountable, transparent, and will not be permanently dominated by a particular group of people in the community.

This thesis has also recommended the justifications of BS between the communities. The thesis has addressed that the criticisms of how the BS can be justifiably determined between the communities when one community receives a benefit sharing while the others who live nearby would not. As consequence, one community will have extra money to spend on things that the law allows the money to be used for whereas the other communities cannot. The community who own the biological resources might see that they should be entitled as a sole owner of biological resources to receive benefits sharing arising out of the utilization of

biological resources. This thesis agree that the owner of the biological resources shall legally receive a benefit sharing however it would not be fair especially when the community where is not far apart would be financially differentiated because they don't have any valuable biological resources. This can be seen that the benefit sharing scheme might not be optimally implemented as designed for because it causes the differences among the communities financially and socially, therefore, this thesis would like to recommend an approach to diminish the size of the gap. As can be seen from the above paragraph, there are two questions need to be addressed in order to answer the above problem. Those are the question of who own the biological resources and the issue of how the BS can also be shared with the other communities who do not own the valuable biological resources.

Firstly, the issue of ownership of biological resources is important because it can necessarily be used to identify the owner of the biological resources before the benefit sharing is to be determined and agreed. Even though, the ownership is the most appropriate basis for PIC and BS but is not sufficient in itself because it is a good method of dealing with the first stage of assigning rights and calculating benefits, but there should also be another process of ensuring that sharing of benefits is much wider in the general community. Therefore, it is necessarily important to firstly address how we can we assure the grant of ownership of biological resources is fairly determined. This thesis believes that in order to address this question, there shall be a National Information System Unit (NISU)[378] under the supervision of the national competent authority to enlist all the valuable biological resources biological resources, their by-products, innovations and practices associated with their use and applications and knowledge and the traditional use of biological resources in order to serve as prima facie evidence of ownership of the resources; to serve as evidence of prior art, which might be used to challenge patent applications; and to protect traditional knowledge, innovations or practices against continuing erosion and promote their revitalization. In order to do so, there are three ways of the lists of the valuable biological resources can be collected. The first one would be the national

378 The recommendation of establishing a National Information System can be seen in the article 64 of African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the regulation of access to biological resources.

competent authority will establish its own internal agency to survey and list all biological resources and practices and pinpoint where it can be found. The second one would be the local authority such as the TAO will give a formal notification to the National Information System Unit of the valuable biological resources and practices those can be found in the area. The third one would be the bio-prospector can inform the NISU of the valuable biological resources and where they can find them. As consequences, the national competent authority can acquire the information of the biological resources and the practice of the use of biological resources as a database. In order to bring into a definite end of who would be entitled to own the biological resources and practice, the competent authority will need to set up an ad hoc committee to determine the criterion of ownership and scientifically decide who would be the owner of the biological resources and the practice of the use of such resources. Therefore, at this stage, the process of identifying the ownership of the resources and practices will be fairly, scientifically, and justifiably determined.

Secondly, there is a question of how to bridge the differences between the communities with regards to the benefit sharing issue. There are two assumptions that this thesis sees it is necessary to hold as an opinion. First, the owner of the biological resources shall legally receive the benefit sharing arising out of the utilization of resources and give the PIC on the utilization of biological resources and its practices based on the two-tier system. Secondly, even though the community nearby or far away is not the owner of biological resources as determined by above process but they should not be totally left out of the bio-prospecting regime because there will be a differentiation between the communities. Therefore, this thesis would like to recommend that the national competent authority shall establish the Bio-prospecting Trust Fund as a National Fund which will be allocated to or requested by the communities though out the country as a national fund. The objective of the Fund can be set and used for, for example, the management and conservation of heritage sites and biological diversity or compensating or rehabilitating and socio-economic development of areas from and apart from where such biological resources or knowledge associated. The percentage of money obtained for the trust fund which from the benefit sharing arising out of the utilization of resources shall be determined

on the case by case basis or can be specified in the legislation[379] depends on how the lawmaker would like it to be. For the allocation of the fund to the communities, it shall be determined on the case by the case basis depends upon the types of the activities, plans, or programs with regards to bio-prospecting issues as it will be determined by a special committee set up by the National Competent Authority. The example of the trust fund can be seen in the article 85 of the Biodiversity Act of Africa in which establishment of bio-prospecting Trust fund will receive all moneys arising from benefit-sharing agreements and material transfer agreements, and due to stakeholders must be paid, and from which all payments to, or for the benefit of, stakeholders must be made. In addition, the National Government can also contribute the money to this fund in order to use in the business of National Biodiversity Authority, or to keep any grants or charges by the National Biodiversity Authority in order serve the objective of Biodiversity Legislation. This could be learnt from the example of India Biodiversity Act[380] which gives the money from the Fund for different purposes such as the conservation of biological resources and development of areas from where such biological resources or knowledge associated has been accessed or socio-economic development of areas referred to in consultation with the local bodies concerned.

Since this thesis had mentioned that Thailand has no single authority to deal with the problem of bio-prospecting. Therefore, this thesis also recommended how the Competent Authority can be put in place. This thesis is of the opinion that at the community level, the Tambon Administrative Organization (TAO is equivalent to

379 The specification of the money that go to the trust fund can be seen in the article 8 of Peru act as follows: Percentage accruing to the Fund for the Development of Indigenous People: A percentage which shall not be less than ten per cent of the value, before tax, of the gross sales resulting from the marketing of goods developed on the basis of collective knowledge shall be set aside for the Fund of the Development of Indigenous Peoples provided for in Articles 37 et seq. The parties may agree on a greater percentage according to the degree of direct use or incorporation of the said knowledge in the resulting end product and the degree to which the said knowledge contributed to the reduction of the cost of research and development work on derived products, among other things.

380 Article 27: Application of National Biodiversity Fund. 27. (1) There shall be constituted a Fund to be called the National Biodiversity Fund and there shall be credited thereto--a) any grants and loans made to the National Biodiversity Authority under section 26, 15 (b) all charges and royalties received by the National Biodiversity Authority under (his Act; and (c) all sums received by the National Biodiversity Authority from such other sources as may be decided upon by the Central Government. (2) The Fund shall be applied for- (a) channelling benefits to the benefit claimers; (b) conservation of biological resources and development of areas from where such biological resources or knowledge associated thereto has been accessed; (c) socio-economic development of areas referred to in clause (b) in consultation with the local bodies concerned.

Sub-district Administrative Organization) can act as an official agent for the community for the PIC and BS decision and for the national level, it would be the Office of Natural Resources and Environmental Policy and Planning under the Ministry of natural Resources and Environment.

This can be explained when Thailand has enacted the TAO Act B.E. 2537 (1994) which established the Tambon Administrative Organization (Sub-district Administrative Organization) in order to implement the decentralization policy and to take a step forward in a realization of a village self management policy[381]. There are two lines of work for TAO; the first one is to coordinate and to carry out plans and projects designed by government agencies and the second one is to carry out eight obligatory functions and four optional items of work including to protect and to preserve of the environment and natural resources in their jurisdictions. The TAO is composed of two elected representatives from each village in a *tambon* (sub-district). In the TAO itself, it is divided into two parts which are the council comprised of all elected member and the executive part which is composed of three member of the elected out of and by the TAO members[382]. For the TAO's revenue, there are multiple routes of TAO's revenue as can be divided into three categories as follows: taxes and fees, state support budget, and TAO income. For the taxes and fees, they can come from taxes of the land, building, sign board, duties from charges, surcharges, fees, fines, licenses, permits, Value added tax such as slaughterhouse licenses, gambling licenses, special business taxes, liquor taxes, excise taxes, automobile/ vehicle registration taxes. For the TAO income, it can come from TAO own properties, provision of infrastructure facilities and services, donations, and etc. Therefore, the TAO can be seen as a decision maker at the community level to give the consent on the PIC and BS on behalf of the community with regards to the bio-prospecting.

For the state's competent authority, it is of the opinion that the Thai government has already had the competent authority who can serve both as a competent authority that monitor the legislation and is in charge of approving the PIC and BS agreement. According to the new government restructuring program, the

381 Chaiyan Rajchagool, Tambon Administrative Organization: Are the People in the Dramatis Personae or in the audience?

382 However, the provincial governor still direct and oversee the operation of TAO in order to ensure that it functions within the framework of law and rules laid down by the legislations

Office of Natural Resources and Environmental Policy and Planning (ONEP) under the Ministry of Natural Resources and Environment which serves as the national focal point for Convention on Biological Diversity (CBD) and servers as the National Biodiversity Reference Unit (NBRU) to ASEAN Regional Centre for Biodiversity Conservation (ARCBC) has the responsibility to formulate policies and integrated plans, propose the measures on administration and management of natural resources and environment and coordinate to transform them into practice in order to integrate system of an administration and management of natural resources and environment, based upon area, function and participation principle, to promote the balance between utilization and preservation, rehabilitation and conservation of natural resources, as well as effective coordination on utilization for sustainable development with acceptable environmental impacts, and to strengthen capability of local government to administrate and manage natural resources and environment[383] could be served as a competent agency to monitor the implementation of the legislation, the PIC, and BS through the establishment of the national board who will have a duty to approve the PIC and BS. As previously mentioned in the previous chapter that the board should be comprised of different groups of people both the government officials, academic, expert, renowned non-governmental groups, representative of the public organization, local community because the board can give different perspectives when the biodiversity law is implemented and especially when it comes to decision of granting or approving a permit to access or on the benefit sharing agreement.

Therefore, it can be seen that Thailand has readily furnished with the agencies who can act as an agent to decide about the PIC and BS for the protection of bio-prospecting problem both locally and nationally. However, the TAO Act still need to be amended on the details of how the TAO can be effectively and efficiently performed with regards to the bio-prospecting problem such as the establishment of an independent committee on bio-prospecting, how the BS can be utilized, and etc in order to give an efficient operation of their duties.

383 These responsibilities have been excerpted from the Ministerial Regulation "Ministerial Subordinates of the Office of Natural Resources and Environmental Policy and Planning, Ministry of Natural Resources and Environment in B.E. 2545 (2002)

2.3 Social Impact Assessment (SIA)

With regards to SIA, this thesis is of the opinion that the Social Impact Assessment could be used both, as explained in the chapter 6, as a tool to justify BS scheme and a tool to justify access and use of biological resources. Even though SIA has not been widely used in Thailand but the acceptance of the other assessment method has been officially visualized as can be seen from the acceptance of the Environmental Impact Assessment[384] as an official assessment for the environmental protection. Therefore, if SIA can be put into the legislation as an official tool to assess the grant of an access or use of biological resources as EIA and to assess the BS decision, then SIA would both qualitatively and quantitatively be able to assure the community and the competent authority to mutually agree with the result academically and by using reason in an orderly cogent fashion. SIA has been introduced on the grounds that SIA can be used by authority concerned as a safeguard tool to ensure that the permission to be made for the access and use of biological resources will be rationale by the owner of biological resources when it applies for the commercial exploitation. In addition, it has also been recommended that SIA can also be used to calculate quantitatively and qualitatively the benefits arising out of utilization of biological resources before the term have been agreed. The example of how SIA can be put in place has been specifically explained in Chapter 6.

It should be noted that this thesis has reviews Bio-diversity legislation to re-affirmed that biodiversity legislation is an option for the problem of bio-prospecting and particularly to escape political atmosphere at the TRIPs council and the rigidity of TRIPs articles. The review of biodiversity legislation has been reviewed to examine and give comparisons of different types of legislations those related to biological

384 The first mandatory provision of the EIA was issued in 1981 Under Sec 46 of the Enhancement and Conservation of Nation of National Environmental Quality Act 1992. The Ministry of Science, Technology, and Environment with the approval of National Environment Board (NEB) has the power to specify by notification the type and size of projects or activities requiring EIA. (Nowadays, the responsibility of the EIA goes to the Office of Natural Resources and Environmental Policy and Planning (ONEP) under the Ministry of Natural Resources and Environment) EIA has to be prepared by a consulting firm which is registered by OEPP and has to be submitted to OEPP for preliminary review before final decision on the report will be made by the Expert Review Committee. Environmental Impact Evaluation Division (EIED) of OEPP will be responsible for examine the environment impact assessment report and related documents filed there with and also the preliminary review. The report together with the preliminary comments will then be proposed to the Expert Review Committee for final consideration. Therefore, the SIA can be introduced through the acceptance as the EIAs.

resources from around the world in order to find common grounds and differences in order to see how it would be best for this thesis to apply to the biodiversity legislation in Thailand for the problem of bio-prospecting. The review of biodiversity legislation has shown to the reader that the legislation can be designed and equip with the necessarily conditions and tool to address the problem of bio-prospecting. One of the strengths of the biodiversity legislation is that it is more flexible to address the issues those relate to biological resources, not only the problem of bio-prospecting but problems those relate to biological resources whereas if we introduce any conditions to the patent law, then if there is anything or upcoming issues in the future, there might be a problem to keep the issues up to date due to political factors at the WTO. It is submitted that the Biodiversity Laws will be of great benefit to the country to, first, escape the rigidity of the TRIPs agreement and, second, to recognize that the country has her own sovereign rights to determine and desire the use of their biological resources.

This thesis has concluded that the PIC and BS are clearly accepted as conditions which can be used for the bio-prospecting problem. There are two options to put these conditions either as criteria of patentability or in a new legislation which directly address the bio-prospecting problem. For the option to put it in criteria of patentability it might be politically difficult as mentioned in the previous chapter, therefore, to put in the Biodiversity Legislation might the only option left in order to control the use and access of the biological resources. These conditions will be best put though a new legislation. The new legislation will be equipped with conditions and tools in order to control the access of biological resources by stopping the inventor taking away the biological resources before they even apply for the patent protection. For the SIA, it seems to be that it is up to country how the SIA would be used. The SIA can be used as a problem identifier whether the authority shall grant the use and access of the biological resources or to use it as a condition to justify the Benefit sharing scheme or both in which it is all depend on the member to see which option would be of best benefit for the country.

This thesis also contains recommendations for how the competent authorities can deal with the problem of bio-prospecting. The National Competent Authority and the Tambon Administration Organization (Local Organization) should have a duty as

official agents and as co-owners of biological resources to decide via the formal conditions and tool to give a permission of access and rationale the benefit sharing arising out of the utilization of biological resources. In addition, it is believed that there should be a National Information System Unit (NISU) under the supervision of the national competent authority to enlist all the valuable biological resources biological resources, their by-products, innovations and practices associated with their use and applications and knowledge and the traditional use of biological resources in order to serve as prima facie evidence of ownership of the resources; to serve as evidence of prior art, which might be used to challenge patent applications; and to protect traditional knowledge, innovations or practices against continuing erosion and promote their revitalization. Lastly, patent law should also be amended in order strengthen the Biodiversity Legislation by adding a clause with regarding the legitimacy of acquiring biological resources.

This thesis has concluded that in order to address the problem of bio-prospecting under the TRIPs agreement, it would be best for Thailand to enact a new "Biodiversity Legislation". This thesis believe that the conditions and tool which are PIC, BS, and SIA respectively equipped in the biodiversity legislation will help Thailand to deal with the problem of bio-prospecting effectively and efficiently under international law and keep up Thailand competitiveness and benefit from bio-prospecting activities and technological development in the capitalistic world.

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