

CHAPTER 6

Country specific Legal provision for Governance of Genetic Resources and Traditional Knowledge

6.1 Legal provisions for protection of Genetic Resources and Traditional Knowledge

Since TRIPS does not have any reference to Traditional Knowledge, countries have developed their own *sui-generis* system to tackle the issue of protection of traditional knowledge associated with biological resource, for example, countries like Brazil, Ethiopia, Kyrgyzstan, Peru, Portugal, and Thailand have their own *sui-generis* system enacted for protection of Traditional knowledge. Genetic resources and disclosure requirements have been enacted by countries like Belgium, China, Costa Rica, Cuba, Denmark, European Union, Germany, Italy, Norway and Sweden

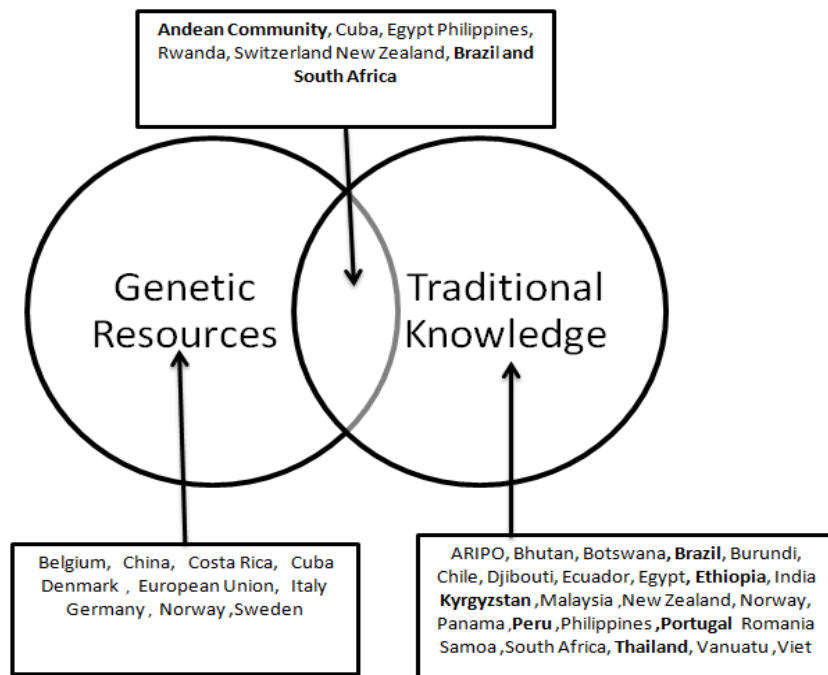


Figure 1 Countries with legal provisions related to Traditional Knowledge and Genetic Resources

A few countries protecting Genetic Resources associated with Traditional knowledge are Andean Community, Cuba, Egypt, New Zealand, Philippines, Rwanda South

Africa , Brazil and Switzerland.¹ Further protection has been provided by the countries of Andean Community, Brazil ,South Africa, Ethiopia, Kyrgyzstan, Peru, Portugal and Thailand through *sui-generis* system for Genetic Resources and Traditional knowledge protection , access and benefit sharing as shown in Figure 1 and Table 1

Countries with legal provisions related to Traditional Knowledge and Genetic Resources		
Traditional Knowledge	Genetic Resources	Traditional Knowledge Genetic Resources
ARIPO, Bhutan, Botswana, Brazil, Burundi, Chile, Djibouti, Ecuador Egypt Ethiopia India Kyrgyzstan Malaysia New Zealand, Norway, Panama Peru Philippines Portugal Romania Samoa South Africa Thailand Vanuatu Viet Nam	Belgium China Costa Rica Cuba Denmark European Union Germany Italy Norway Sweden	Andean Community , Cuba, Egypt Philippines, Rwanda, Switzerland New Zealand, Brazil and South Africa

Table 1 Countries with legal provisions related to Traditional Knowledge and Genetic Resources .(The countries shown in bold have enacted sui-generis system for Genetic Resources and Traditional knowledge)

6.2 Disclosure of Origin of Biological Material/ Genetic Resource in a Patent

TRIPS allows patents for biological resource but does not mandate origin of disclosure of the genetic resource. The developed countries have technology to use TK associated with biological diversity, extract the bioactive compounds and patent it without mentioning the source of origin. With ex situ collections of plant genetic material collected in Gene Bank before the enactment of CBD, the country of origin

¹Legislative texts were searched from WIPO Lex (WIPO's collection of laws) available at <http://www.wipo.int/tk/en/databases/tklaws/>

of genetic resource will never be able to provide Prior Informed Consent if the genetic material is directly taken from the Gene Bank. The issue of Disclosure of Origin should be dealt with CBD through protocol initiation.

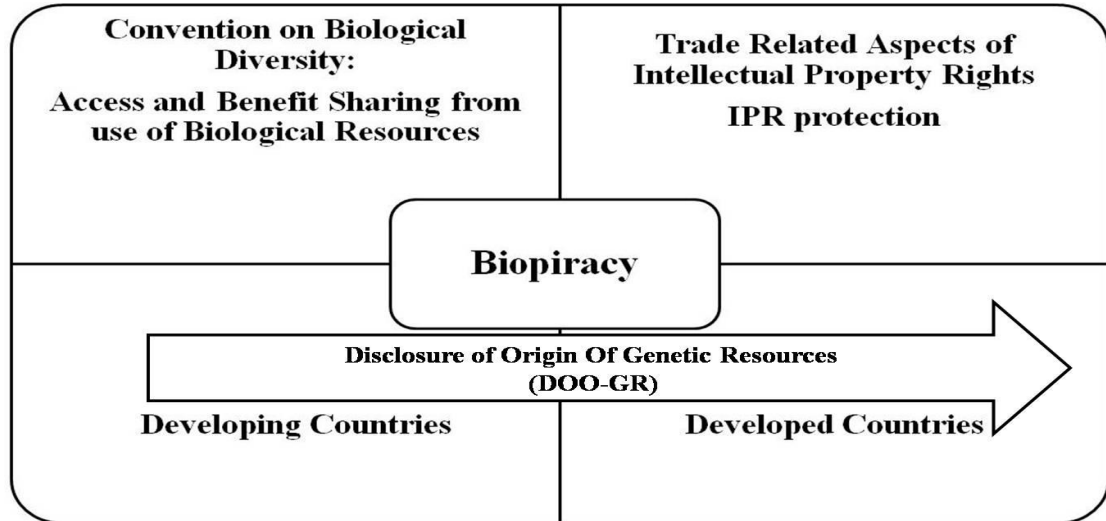


Figure 2 Biopiracy , CBD and TRIPS and Disclosure of Origin of Genetic Resources used in Patent Application

6.3 Legal Provisions for Disclosure of Origin of Biological Material

6.3.1 Belgium and Disclosure of Origin of Biological Material Belgium has taken Convention on Biological Diversity² to heart and on April 28, 2005, modified the law of March 28, 1984 on Patents particularly biotechnological patents to a statement of the geographical origin of biological material of plant or animal origin³.

6.3.2 Denmark and Disclosure of Origin of Biological Material Denmark through Order No. 93 of January 29, 2009 on Patents and Supplementary Protection

² Van Overwalle, G. (2002). Belgium goes its own way on biodiversity and patents. *European Intellectual Property Review (EIPR)*, 233-236.

³ Law of April 28, 2005 modifying the Law of March 28, 1984 on Patents in particular the Patentability on Biotechnological Inventions: According to Article 15 §1er. of Law of April 28, 2005 modifying the Law of March 28, 1984 on Patents in particular the Patentability on Biotechnological Inventions, The patent application shall contain: (6) a statement of the geographical origin of biological material of plant or animal origin from which the invention was developed, when the latter is known.

Certificates⁴ states that disclosure of geographical origin biological material of vegetable or animal origin, should be contained in the patent application

6.3.3 Germany and Disclosure of Origin of Biological Material Germany through its Patent Act ⁵ through Section 34a states Disclosure requirement of origin of biological material from animal or plant origin

6.3.4 China and Disclosure of Origin of Biological Material China through Article 26⁶ of Patent Law of the People's Republic of China (as amended up to the Decision of December 27, 2008, regarding the Revision of the Patent Law of the People's Republic of China) mandates direct and original source of the genetic resources in Patent application. Rule 26⁷ of " Rules for the Implementation of the Patent Law of the People's Republic of China (promulgated by Decree No. 306 of the State Council of China on June 15, 2001, and revised by the Decision of January 9, 2010, of the State Council on Amending the Rules for the Implementation of the Patent Law of the

⁴ Order No. 93 of January 29, 2009 on Patents and Supplementary Protection Certificates, Part I Chapter 2; Article 3(4) reads " If an invention relates to or makes use of a biological material of vegetable or animal origin, the patent application shall contain information about the geographical origin of the material if the applicant is aware thereof. If the applicant is not aware of the geographical origin of the material, that shall appear from the application. Lack of information about the geographical origin of the material or about the applicant's non-awareness thereof shall not affect the examination and other processing of the patent application or the validity of the rights conferred by the granted patent."

⁵ Patent Act of Germany, Amended by the Law of July 31, 2009, Section 34a reads " Should an invention be based on biological material of plant or animal origin or if such material is used therefor, the patent application is to include information on the geographical origin of such material, if known. This shall not prejudice the examination of applications or the validity of rights arising from granted patents."

⁶ With regard to an invention-creation accomplished by relying on genetic resources, the applicant shall, in the patent application documents, indicate the direct and original source of the genetic resources

⁷ Rule 26 of " Rules for the Implementation of the Patent Law of the People's Republic of China (promulgated by Decree No. 306 of the State Council of China on June 15, 2001, and revised by the Decision of January 9, 2010, of the State Council on Amending the Rules for the Implementation of the Patent Law of the People's Republic of China)" reads "The genetic resources referred to in the Patent Law mean any material taken from human, animal, plant or microorganism, containing genetically functioning units with actual or potential value; the invention-creation accomplished depending on the genetic resources means those invention-creation of which the accomplishment uses the genetic function of genetic resources."

People's Republic of China)" defines genetic resource, while Rule 53⁸ states rejection of patent application on non compliance.

6.3.5 Norway and Disclosure of Origin of Biological Material Section 8b of Patents Act⁹ (Act No. 9 of December 15, 1967, as amended up to Act No. 8 of July 1, 2010) mandates information on use and origin of biological material. It goes further in asking information related to Prior Informed Consent was obtained

6.3.6 Sweden and Disclosure of Origin of Biological Material

Article 5a of Regulation (2004:162)¹⁰ Amending the Patents Decree of Sweden mandates information related to disclosure of origin of an invention based on biological resource if the origin is known

⁸ Rule 53 of " Rules for the Implementation of the Patent Law of the People's Republic of China (promulgated by Decree No. 306 of the State Council of China on June 15, 2001, and revised by the Decision of January 9, 2010, of the State Council on Amending the Rules for the Implementation of the Patent Law of the People's Republic of China)" reads [...] an application for a patent for invention shall be rejected by the Patent Administration Department under the State Council after examination, [...] where the application does not comply with the provisions of Article 26 [...] of the Patent Law."

⁹ Section 8b of Patents Act (Act No. 9 of December 15, 1967, as amended up to Act No. 8 of July 1, 2010) states "If an invention concerns or uses biological material, the patent application shall include information on the country from which the inventor collected or received the material (the providing country). If it follows from the national law in the providing country that access to biological material shall be subject to prior consent, the application shall state whether such consent has been obtained. If the providing country is not the same as the country of origin of the biological material, the application shall also state the country of origin. The country of origin means the country from which the material was collected from its natural environment. If the national law in the country of origin requires that access to biological material shall be subject to prior consent, the application shall state whether such consent has been obtained. If the information set out in this subsection is not known, the applicant shall state that. The duty to disclose information under the first and second paragraphs applies even where the inventor has altered the structure of the received material. The duty to disclose information does not apply to biological material derived from the human body. Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code § 166. The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents."

¹⁰ Article 5a of Regulation (2004:162) Amending the Patents Decree states "If an invention concerns biological material of plant or animal origin or if it uses such material, the patent application shall include information on the geographical origin of such material, if this is known. If the origin is not known, this shall be indicated. Lack of information on the geographical origin or on the knowledge of the applicant regarding the origin is without

6.3.7 Italy and Disclosure of Origin of Biological Material

Article 170 *bis* of Industrial Property Code (Legislative Decree No. 30 of February 10, 2005, as amended up to Legislative Decree No. 131 of August 13, 2010) mandates declaration of information related to disclosure of origin of an invention based on biological resource¹¹. Italy goes further ahead to declare the origin of biological resource with reference to country of origin

6.3.8 European Union Disclosure of Origin of Biological Material

Paragraph 27 of the Preamble of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of biotechnological inventions allows for declaration of biological material of plant or animal origin with information on geographical origin if known by the applicant¹²

6.3.9 Cuba, Traditional Knowledge and origin of Genetic Resource

Cuba Article 31.1¹³ of Decree-Law No. 291 of November 20, 2011 on the Protection of Plant Varieties, states furnishing the application with document stating country of

prejudice to the processing of the patent application or the validity of the rights arising from a patent granted.”

¹¹ Article 170 bis of Industrial Property Code (Legislative Decree No. 30 of February 10, 2005, as amended up to Legislative Decree No. 131 of August 13, 2010) reads” The provenance of biological material of animal or plant origin, which is the basis of the invention, is to be declared together with the application of the patent both with reference to the country of origin, in order to verify compliance with import and export legislation, and in relation to the biological organism from which it was isolated”

¹² Paragraph 27 of the Preamble of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of biotechnological inventions reads “Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.”

¹³ Article 31.1 of Decree-Law No. 291 of November 20, 2011 on the Protection of Plant Varieties, of the Republic of Cuba states "To request a breeder's right, the applicant filed with the Office of the corresponding application, composed of the following documents:[...](e) the document indicating the country of origin and source of the original plant material and associated traditional knowledge and practices, and these references on the plant variety in question; this requirement extends hybrids; (f) where the plant variety is derived from an initial plant material from which the territory of the Republic of Cuba is a country of origin or express consent it is present in domesticated and cultivated in the country, a copy of the document attesting for access to such material or starting materials issued by competent

origin and associated traditional knowledge, and express consent where biological resource is from Cuba. Article 26.1(j)¹⁴ of Decree-Law No. 290 of November 20, 2011 on Inventions and Industrial Designs and Models requires express authorisation for access to biological material where Cuba is country of Origin or the biological resources is present or domesticated in the country. Article 26.1(k)¹⁵ of Decree-Law No. 290 of November 20, 2011 on Inventions and Industrial Designs and Models states if the biological resource is not obtained from Cuba, the country of origin and source along with informed consent prior to access should be stated

6.3.10 Costa Rica and Disclosure of Origin of Biological Resources Costa Rica¹⁶ allows consultations with Technical Office of the Commission, who can prohibit registration of a patent or protection of innovation, hence before granting protection of intellectual or industrial property to innovations involving components of biodiversity property

authority in accordance with current legislation on the subject; g) otherwise as provided in the preceding paragraph, a statement in which it expresses that the material is a source of start of plant variety has not been obtained in the territory of the Republic of Cuba, which has been obtained consent to access."

¹⁴ Article 26.1 of Decree-Law No. 290 of November 20, 2011 on Inventions and Industrial Designs and Models states "To obtain a patent, the applicant filed with the Office of the relevant application containing the following documents:[...](j) copy of the previous and express authorization for access to biological material, issued by the competent authority in accordance with current legislation on the subject, when the invention relates to such material, including genetic and parts or derivatives that Cuba is a country of origin or present in domesticated and cultivated in the country"

¹⁵ Article 26.1 (k) of Decree-Law No. 290 of November 20, 2011 on Inventions and Industrial Designs and Models states that "Statement expressing that the biological material to which the invention relates has not been obtained in the territory of the Republic of Cuba, in which case the country of origin and source of biological material and associated traditional knowledge must be indicated to these and informed consent prior to access"

¹⁶ Article 80 of Law No. 7788 on Biodiversity (as last amended by Law No. 8686 of November 21, 2008) reads "Obligated prior consultation Both the National Seed Office and the Registers of Intellectual and Industrial Property, obligatorily should consult the Technical Office of the Commission before granting protection of intellectual or industrial property to innovations involving components of biodiversity property. Always provide the certificate of origin issued by the Technical Office of the Commission and prior consent Justified opposition from the Technical Office will prohibit registration of a patent or protection of innovation"

6.4 Legal Source of Countries on Traditional Knowledge in Patent document

6.4.1 The African Regional Industrial Property Organization (ARIPO) and Swakopmund Protocol

Section 2 of, Swakopmund Protocol¹⁷ on the Protection of Traditional Knowledge and Expressions of Folklore of the African Regional Industrial Property Organization, a *sui-generis* legislation defines “traditional knowledge” as "any knowledge originating from a local or traditional community that is the result of intellectual activity and insight in a traditional context, including know-how, skills, innovations, practices and learning, where the knowledge is embodied in the traditional lifestyle of a community, or contained in the codified knowledge systems passed on from one generation to another. The term shall not be limited to a specific technical field, and may include agricultural, environmental or medical knowledge, and knowledge associated with genetic resources." Section 6¹⁸ defines the beneficiaries of traditional knowledge shall be holders of traditional knowledge who create, preserve and transmit knowledge in a traditional and intergenerational framework. Swakopmund Protocol provides exclusive rights to owners of traditional knowledge to authorize exploitation of traditional knowledge through Section 7.1 and empowers the holders of traditional knowledge to prevent anyone from exploiting their traditional knowledge as a product from manufacturing, importing, exporting, offering for sale, selling or using beyond the traditional context the product. Mere possession of the product for offer of sale too can be stopped without prior informed consent through Section 7.2¹⁹.

¹⁷ Swakopmund Protocol henceforth

¹⁸ Section 6 of *sui-generis* legislation, Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore, defines Beneficiaries of protection of traditional knowledge as "The owners of the rights shall be the holders of traditional knowledge, namely the local and traditional communities, and recognized individuals within such communities, who create, preserve and transmit knowledge in a traditional and intergenerational context in accordance with the provisions of section 4."

¹⁹ Section 7.3, of Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore, defines the term "exploitation" with reference to traditional knowledge as any of the following acts: (a) Where the traditional knowledge is a product: (i) manufacturing, importing, exporting, offering for sale, selling or using beyond the traditional context the product; (ii) being in possession of the product for the purposes of offering it for sale, selling it or using it beyond the traditional context; (b) Where the traditional knowledge is a process: (i) making use of the process beyond the traditional context; (ii) carrying out the acts referred to under paragraph (a) of this subsection with respect to a product that is a direct result of the use of the process.

6.4.2 Bhutan and Traditional Knowledge Article 3(d)²⁰ of the Biodiversity Act of Bhutan 2003, defines Traditional knowledge²¹ as either been transmitted from one generation to generation, or pertains to a particular clan or community, or is collectively originated and held. Article 37²² of the Act mandates prior informed consent for traditional knowledge from traditional owners and empowers the owners of Traditional Knowledge through Article 38²³ to reject the application or to accept the application and enter negotiations for benefit sharing.

6.4.3 Botswana and Traditional Knowledge Section 2 of Industrial Property Act, 2010 defines traditional knowledge as " an idea, knowledge, practice, use or invention, written or unwritten which, may be associated to biological diversity, is a cultural, traditional or spiritual belief or value of a group of people". Section 117 Industrial Property Act, 2010 defines rights conferred by traditional knowledge of ownership, collective ownership. Interestingly Section 117 (4)²⁴ allows individuals from different countries other than Botswana to register and acquire rights over traditional knowledge. Section 121 (a) confers specific rights to holders of traditional knowledge as patents like exclusive rights on a product like the right to prevent third parties without consent from making, using, stocking, offering for sale, selling, commercializing, importing or exporting the product. Section 121 (b) provides the right to prevent third parties from reproducing, multiplying or preparing for

²⁰ Article 3(d) of the Biodiversity Act of Bhutan 2003 states " The Traditional Knowledge includes any knowledge that generally fulfills one or more of the following conditions (i) Is or has been transmitted from generation to generation (ii) Is regarded as pertaining to a particular traditional group, clan and community of people in Bhutan (iii) Is collectively originated and held

²¹ Article 51(q) of the Biodiversity Act of Bhutan 2003 defines Traditional Knowledge as " the knowledge, innovation and practices of local communities relating to the use, properties, values and processes of any biological and genetic resources or any part thereof "

²² Article 37 of the Biodiversity Act of Bhutan 2003 states "The applicant shall obtain the prior informed consent of the traditional owners of the Traditional Knowledge for use of Traditional Knowledge for a non-customary use."

²³ Article 38 of the Biodiversity Act of Bhutan 2003 states on the Appraisal of application "The owners of the Traditional Knowledge must decide whether (a) To reject the application (b) To accept the application and enter into negotiations for a written authorized user agreement in relation with the application containing the appropriate benefit sharing arrangements."

²⁴ Section 117 (4) of Industrial Property Act, 2010 states "An applicant community which comprises of individuals from different countries including Botswana, shall have the right to register and acquire rights over traditional knowledge in Botswana and in the other countries."

reproduction through an offer of sale, sale, importing, exporting or any form of commercialization for a domesticated animal, plant or any microorganism . Section 121 (c) prevents third parties without consent for a design or an object of aesthetic nature or a handicraft from making or reproducing an object with similar configuration.

6.4.4 Brazil and Traditional Knowledge Article 7 (I) of Provisional Act No. 2.186-16, dated August 23, 2001 defines Genetic Heritage as " information of genetic origin contained in samples of all or part of plant, fungal, microbial or animal specimens, in the form of molecules and substances deriving from the metabolism of such living beings and extracts obtained from such organisms, live or dead, encountered *in situ*, including domestic situations, or kept in *ex situ* collections after *in situ* collection within the national territory, on the continental shelf or in the exclusive economic zone". Article 7 (III) of Provisional Act No. 2.186-16, dated August 23, 2001 defines local community as " human group, including descendants of Quilombo communities, differentiated by its cultural conditions, which is, traditionally, organized along successive generations and with its own customs, and preserves its social and economic institutions". Article 9 of Provisional Act No. 2.186-16, dated August 23, 2001 on Protection to Associated Traditional Knowledge to the indigenous communities and local communities that create, develop, hold or conserve traditional knowledge associated to genetic heritage are assured the right to have acknowledged origin of access to Traditional Knowledge in all publications uses, and disseminations, and prevent third parties for using, testing, researching associated traditional knowledge, disseminating, transmitting or forwarding data associated with traditional knowledge, receive benefits from economic use directly or indirectly. Article 30 defines punishment with sanctions like warning, fine imposition, Confiscation of samples, products, suspension of sales, cancellation of patent, lisenca, ban on signing contracts with public authority for 5 years for contravening with the provisions of the Act for usage of genetic heritage and associated traditional knowledge with fine varying from R\$200 (two hundred reais) to R\$100,000 (one hundred thousand reais) for natural persons, as referred to in subparagraph II of paragraph §1, and fine from R\$10,000 (ten thousand reais) to R\$50,000,000 (fifty million reais) for offence committed by legal entity.

6.4.5 Burundi and Traditional Knowledge Article 2 of Law No. 1/13 of July 28th, 2009 on Industrial Property defines Traditional knowledge as "the ideas, practices, uses and inventions which may or may not be linked to biological diversity, created by local indigenous communities in a traditional and informal manner, in response to the challenges posed by their material and cultural environment, and which serve as identifiers for these communities." Article 247 of Law No. 1/13 of July 28th, 2009 on Industrial Property defines elements of Traditional Knowledge as " inventions or other technical ideas, uses, designs, equipment, tools and instruments that can be used in the production of products and services, including the processes, equipment and products used to obtain them, as well as plants domesticated or grown or animal species and microorganisms; knowledge of the properties of biological resources as well as combinations of such resources; methods, processes and products relating to the fields of medicine, agriculture, food and textiles as well as the other products and services with a practical or spiritual function." **Article 261** states "Local communities' collective rights in the traditional knowledge registered shall be of an economic and moral nature."**Article 262 states** "With regard to the traditional knowledge protected under this Law, local communities shall enjoy the following exclusive rights: the right to prevent third parties from manufacturing, using, storing, offering for sale or selling this product, or from importing or exporting this product for these purposes without the holder's consent if the subject matter of the protection is a product; the right to prevent third parties from using the process to store, offer for sale or sell products obtained directly or indirectly via this process, or from importing or exporting such products for these purposes without the holder's consent, if the subject matter of the protection is a process; the right to prevent third parties who do not have the holder's consent from reproducing the species or microorganism, and to prevent third parties from preparing the species or microorganism for purposes of its reproduction or propagation, offering it for sale, sale or any other form of commercialization, import and export, as well as possessing the species or microorganism for one or other of these purposes if the subject matter of the protection is a grown plant species, a domesticated animal species or a microorganism; the right to prevent third parties from manufacturing or reproducing, without the holder's consent, objects which are of a similar configuration in terms of forms, colors, materials and techniques and which display by and large the style and visual impression of the crafts of which they are characteristic if the subject matter of protection is a design or an object of a

functional or esthetic nature, including a crafts element; the right to prohibit for third parties who do not have the holder's consent any type of use, in the language of origin or in any other language, consisting in affixing identical or similar signs to products, or to products related to services, or manufacturing labels, packaging or other materials which reproduce or contain these signs, for commercial purposes or for any other purpose, if the subject matter of protection is a name, symbol, emblem or other distinctive sign of a religious, spiritual, cultural or economic nature." Article 264 states " If a local community opts to keep secret part or all of the inventories of registered traditional knowledge, in accordance with Article 254, it shall be entitled to prevent third parties from disclosing or acquiring without its consent undisclosed traditional knowledge, in a manner contrary to honest business practices, provided that the local community to which the undisclosed registered traditional knowledge belongs has taken reasonable steps to keep it secret."

6.4.6 Chile and Traditional Knowledge Article 3 of Law No. 19.039 on Industrial Property (Consolidated Law approved by Decree-Law No. 3) defines scope of protection as safeguarding and respecting biological and genetic heritage, as well as national traditional knowledge and the Industrial property rights that constitute protectable elements shall be subordinated to acquisition of material with applicable law

6.4.7 Djibouti and Traditional Knowledge Article 34 of Law No. 50/AN/09/6th on the Protection of Industrial Property mentions that description of the invention shall disclose the sources of the invention that has been claimed or obtained from genetic or biological resource or traditional knowledge from a community

6.4.8 Ecuador and Traditional knowledge Article 120 of Intellectual Property Law (Consolidation No. 2006-13) allows conditional protection of inventions in all areas of technology provided that the biological resource and genetic heritage on which the patent has been applied has been acquired lawfully

6.4.9 Egypt and Traditional Knowledge Article 13 of Law on the Protection of Intellectual Property Rights, Law No. 82, 2002 states the inventor to acquire the source involving biological, plant or animal product or traditional medicinal, agricultural, industrial or handicraft knowledge in a legitimate manner. To comply with provisions of Article 13 of Law on the Protection of Intellectual Property Rights,

Law No. 82, 2002, Patent office requires amendments to be made and complied within 3 months of notification; else application shall be considered as withdrawn. Article 3 of Council of Ministers Resolution No. 1366 of 2003 issuing Implementing regulations for Law No. 82 of 2002 on the Protection of Intellectual Property Rights Books One, Two and Four states the application to be accompanied by disclosure documentation, proving the source of material was accessed in a legitimate manner according to legislation applicable in Arab Republic of Egypt

6.4.10 Ethiopia and Traditional Knowledge Article 2 (14) of Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation No. 482/2006 defines "community knowledge" as "knowledge, practices, innovations or technologies created or developed over generations by local communities on the conservation and use of genetic resources.", and local communities Article 2 (9) as a human population living in a distinct geographical area in Ethiopia as a custodian of a given genetic resource or creator of a given community knowledge. Article 5 (2) states ownership to be vested in the local community. Article 6 states the local communities shall have the following rights to regulate access to community knowledge, have inalienable right to use their genetic resources and community knowledge, and the right to share benefit arising out of the use of genetic resource and community knowledge. Article 7 defines the local communities can regulate right to regulate access, prior informed consent, refuse or restrictor withdraw consent when access is detrimental to integrity or natural heritage and be specified by a regulation. Article 9 of Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation No. 482/2006 mandatory provides right to obtain 50% of the benefit monetary benefit arising out of the utilization of their genetic resources and community knowledge. The money obtained shall be put to common advantage of local communities and shall be specified by a regulation. Article 10 ensures protection of community rights over genetic resources even if non-registered shall not make it unprotected by community rights. Presence of genetic resource in a gene bank or any conservation centre shall not affect community rights. Article 11 mandates a written requirement of permit for access of genetic resources or community knowledge based on prior informed consent. Article 12 defines Basic Pre-Conditions of Access of community knowledge and genetic resource, by ensuring a prior informed consent, fair and equitable sharing of benefits arising out of the

utilization of genetic resources and community knowledge accessed, for a foreigner applicant accessing resource will be mandated to present a letter from his national state by a competent authority assuring upholding and enforcing access obligations of the application, also research shall be carried out in Ethiopia, unless impossible, the institution sponsoring the research abroad in such cases shall give a letter of assurance that they observe the access obligations.

6.4.11 India Traditional Knowledge and Biological Resources access Section 2(b) of Biological Diversity Act, 2002 defines "biological diversity" as the "variability among living organisms from all sources and the ecological complexes of which they are part, and includes diversity within species or between species and of eco-systems" and Section 2(c) defines "biological resources" as "plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material". Section 2 (a) defines "benefit claimers" as "the conservers of biological resources, their by-products, creators and holders of knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application." Section 3 mandates prior approval of the National Biodiversity Authority, for access to any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilization by non Indian Citizens, non-resident Indian, corporate not registered in India, corporate registered in India with non-Indian participation in share capital. Section 21(1) 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. Section 21 (2) determines the benefit sharing given either by grant of joint ownership of intellectual property rights, transfer of technology, setting research and development, associating Indian scientists, benefit claimers and the local people with research and development in biological resources and bio-survey and bio-utilization setting up of venture capital fund and payment of monetary compensation and non-monetary benefits to the benefit claimers. Section 3 (p) of Patents Act 1970 as amended by Patents (Amendments) Act 2005 defines "an invention which, in effect, is traditional

knowledge or which is an aggregation or duplication of known properties of traditionally known component or components".

6.4.12 Kyrgyzstan and Traditional Knowledge Kyrgyzstan on the issue of patenting subject matter created on the basis of Traditional Knowledge mandates origin of traditional knowledge through Article 8²⁵ on Patenting of subject-matters created on the base of Traditional Knowledge of “Law of the Kyrgyz Republic on the Protection of Traditional Knowledge” . Through Article 9²⁶ application has to be submitted for right to use registered Traditional Knowledge

6.4.13 Malaysia and Prior Written Consent Article 12(1)(f)²⁷ of Protection of New Plant Varieties Act No. 634 of 2004 mandates prior written consent from local

²⁵ Article 8 on Patenting of subject-matters created on the base of Traditional Knowledge of “Law of the Kyrgyz Republic on the Protection of Traditional Knowledge” states “When patenting the subject-matters created on the base of Traditional Knowledge, materials of the application must contain reveal of origin of Traditional Knowledge which is used as prior art or prototype. The applicant shall indicate the source of making Traditional Knowledge available to the public”

²⁶ Article 9 on Application for registration and granting the right to use Traditional Knowledge or for granting the right to use registered Traditional Knowledge of “Law of the Kyrgyz Republic on the Protection of Traditional Knowledge” states [...] An application shall contain the following: 1) application for traditional knowledge registration and granting the right to use Traditional Knowledge or granting the right to use registered Traditional Knowledge stating the applicant as well as his location and place of residence; 2) specific and complete description of Traditional Knowledge, including: point of origin of Traditional Knowledge (borders of a geographic object); description of genetic resource, which is being used in connection with particular traditional knowledge; field of application and expected positive result of traditional knowledge used; information relevant to previously issued publications regarding a particular traditional knowledge. The following documents shall be attached to the application: 1) An official document granted by the competent authority confirming a practical applicability of Traditional Knowledge and positive result of use thereof in appropriate field of activity. 2) Conclusion of the competent body (bodies) confirming membership of the applicant in a local community and/or is located in geographic object for which Traditional Knowledge is pertained to. In case of filing the application for registration of Traditional Knowledge by State bodies, the said conclusion shall not be required. 3) For foreign applicant a document confirming his/her right for the claimed Traditional Knowledge in the country of origin

²⁷ Article 12(1)(f) of Protection of New Plant Varieties Act No. 634 of 2004 states “An application for the registration of a new plant variety and a grant of a breeder's right shall be made to the Board in the rescribed manner and shall 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”

community or the indigenous people where plant variety is developed from traditional varieties. Article 12(1)(g)²⁸ of Protection of New Plant Varieties Act No. 634 of 2004 mandates supporting documents to be attached that relates to compliance regulating access to genetic or biological resources

6.4.14 New Zealand and Morality Section 14 (3)²⁹ of Patents Act 2013 of New Zealand defines Scope of protection of Inventions contrary to public order and morality as non patentable, where advice can be sought from the Maori advisory committee or any appropriate person

6.4.15 Norway and Biological Resources Norway through Section 166 of Norwegian General Civil Penal Code (Act No. 10 of May 22, 1902, as last amended by Act of August 4, 1995)³⁰ indirectly mentions about imposing penalty where false oral or written testimony is provided as proof. This may be applicable to biological resources and traditional knowledge where information is knowingly hidden

6.4.16 Panama and Benefit Sharing Article 91 (18)³¹ along with Article 146³² of Law No. 35 of May 10, 1996 on Industrial Property mentions Trademarks cannot be

²⁸ Article 12(1)(g) of Protection of New Plant Varieties Act No. 634 of 2004 states “An application for the registration of a new plant variety and a grant of a breeder's right shall be made to the Board in the prescribed manner and shall be supported by documents relating to the compliance of any law regulating access to genetic or biological resources”

²⁹ Section 14 (3) of Patents Act 2013 of New Zealand for Inventions contrary to public order or morality not patentable inventions states “The Commissioner may, for the purpose of making a decision under this section, seek advice from the Māori advisory committee or any person that the Commissioner considers appropriate”

³⁰ Section 166 of Norwegian General Civil Penal Code (Act No. 10 of May 22, 1902, as last amended by Act of August 4, 1995) states “Any person who gives false testimony in court or before a notary public or in any statement presented to the court by him as a party to or legal representative in a case, or who orally or in writing gives false testimony to any public authority in a case in which he is obliged to give such testimony, or where the testimony is intended to serve as proof, shall be liable to fines or imprisonment for a term not exceeding two years. The same penalty shall apply to any person who causes testimony known to him to be false to be given by another person in any of the above-mentioned cases, or who aids and abets thereto”

³¹ Article 91 (18) of Law No. 35 of May 10, 1996 on Industrial Property states “ The following can not be registered as trademarks or elements thereof the words, letters, characters or symbols which are used by the Indian or religious communities or nonprofit organizations, to distinguish the manner of processing the products, the finished products or services, as well as those which constitute the expression of their cult or custom, idiosyncrasy or religious practice, except then the application be made for the benefit of one of the communities or associations to which this numeral refers”

registered that expresses manner of processing , custom unless application is made for the benefit of the community

6.4.17 Peru Collective Knowledge and Patent Invalidation Article 2 (b) of Law No. 27811 of 24 July 2002, introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources defines "Collective knowledge" as "the accumulated, trans-generational knowledge evolved by indigenous peoples and communities concerning the properties, uses and characteristics of biological diversity. The intangible components referred to in Decision 391 of the Commission of the Cartagena Agreement include this type of collective knowledge." Article 2(a) defines "Indigenous peoples" as aboriginal peoples holding rights that existed prior to the formation of the Peruvian State, maintaining a culture of their own, occupying a specific territorial area and recognizing themselves as such. These include peoples in voluntary isolation or with which contact has not been made, and also rural and native communities. The term "indigenous" shall encompass, and may be used as a synonym of, "aboriginal," "traditional," "ethnic," "ancestral," "native" or other such word form. " Article 6 states conditions to collective knowledge for those interested in having access to knowledge to apply for prior informed consent. Article 42 protects rights of indigenous peoples possessing collective knowledge; against the unauthorized disclosure, acquisition or use of that collective knowledge without their consent and in an improper manner provided that the collective knowledge is not in the public domain though in possession of a third party but covered by a safeguard clause. In addition, complementary provisions have been provided for patent developed on the basis of community knowledge , the applicant is obliged to submit a copy of lisencc contract as a prior requirement for grant of rights, failure to comply with obligation can cause a refusal or invalidation of the patent

³² Article 146 of Law No. 35 of May 10, 1996 on Industrial Property states "The following cannot be registered as commercial names, or as any part of them: The words, letters, characters or symbols which are used by native or religious communities or by non-profit associations, to identify the manner in which they process products or to distinguish finished products or services, or those which represent the expression of their cult or custom, idiosyncrasy or religious practice, unless the application be made for its own benefit by one of the communities or associations to which this article refers."

6.4.18 Philippines and Access to Genetic Resources and Indigenous Knowledge

Section 3(h) of the Indigenous Peoples Rights Act of 1997 (Republic Act No. 8371) defines Indigenous Cultural Communities/Indigenous Peoples (ICCs/IPs) as " a group of people or homogenous societies identified by self-ascription and ascription by others, who have continuously lived as organized community on communally bounded and defined territory, and who have, under claims of ownership since time immemorial, occupied, possessed and utilized such territories, sharing common bonds of language, customs, traditions and other distinctive cultural traits, or who have, through resistance to political, social and cultural inroads of colonization, non-indigenous religions and cultures, became historically differentiated from the majority of Filipinos." Section 34 further defines right of Indigenous Knowledge Systems and Practices to Develop own Sciences and Technologies by entitling them recognition to ICCs/IPs of full ownership and control of their cultural and intellectual rights with special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, including derivatives of these resources, traditional medicines and hearth practices, vital medicinal plants, animals and minerals, indigenous knowledge systems and practices, knowledge of the properties of fauna and flora, oral traditions, literature, designs, and visual and performing arts. Section 35 defines access to biological and genetic resources and to indigenous knowledge only with a free and prior informed consent of such communities, obtained in accordance with customary laws of the concerned community related to the conservation, utilization and enhancement of these resources within ancestral lands and domains of the ICCs/IPs.

6.4.19 Portugal and 50 Year Protection for Traditional knowledge

Article 3 Decree-Law No. 118/2002 of 20 April defines Traditional Knowledge as comprising of " all intangible elements associated with the commercial or industrial utilization of local varieties and other autochthonous material developed in a non - systematic manner by local populations, either collectively or individually, which form part of the cultural and spiritual traditions of those populations. That includes, but is not limited to, knowledge of methods, processes, products and designations with applications in agriculture, food and industrial activities in general, including traditional crafts, commerce and services, informally associated with the use and preservation of local varieties and other spontaneously occurring autochthonous

material covered by this Decree". Article 3 mentions scope of Protection of Traditional Knowledge against reproduction or commercial or industrial use only when the traditional knowledge is identified, described and registered in Register of Plant Genetic Resources (RRGV), phrased in a manner to reproduce results by third parties. The owners can also choose to keep traditional knowledge confidential by limiting disclosure. Article 3(6) ensures registration of traditional knowledge to be effective for a period of 50 years from the application there after can be renewed for an identical period. **Access to** and **Allocation of Benefits** are defined by Article 7 for study research subject to prior authorisation by Technical Council of the Ministry of Agriculture, Rural Development and Fisheries on Agrarian Genetic Resources, Fisheries and Aquiculture (CoTeRGAPA) with fair allocation of benefits emanating from prior agreement with the owner. Article 13 mentions about violations and infringement of provisions on Traditional Knowledge described in Article 3 punishable with a fine of between €100 and €2,500. Negligence too is punishable. For violation with a corporate entity, the maximum amount of fines shall be €30,000. with 20%, proceeds reverting to Director General of Crop Protection (DGPC), 10% proceeds to the National Agrarian Research Institute and the DRA concerned, with the remainder 10% going to State funds

6.4.20 Romania and Traditional Knowledge Related Prior Art

Article 16 (1)(c) of Implementing Regulations of the Patent Law No. 64/1991 on the description of the invention mentions description in detail at least one solution considered closest to claimed invention for patent where prior art contains traditional knowledge and its source

6.4.21 Samoa and Patent Biological Resource Disclosure

Section 7 (2)(g) of Intellectual Property Act 2011 of Samoa states that the application for a patent must state whether the invention for which patent is sought is based on knowledge available within any local or indigenous community whether from Samoa or elsewhere. Section 7 (2) (h) mentions about submitting statement disclosing the source and geographical origin of any biological material used for the invention. Section 64(3)(f) mentions application for plant breeder's rights should contain a statement stating whether or not the new plant variety for which protection is claimed

is based on a knowledge available within any local or indigenous community whether from Samoa or elsewhere.

6.4.22 South Africa and Bioprospecting Permit Article 1 of National Environmental Management Biodiversity Act 2004 , defines "indigenous use or knowledge" as "including knowledge of, discoveries about or the traditional use of indigenous biological resources, if that knowledge, discovery or use has initiated or will contribute to or form part of a proposed bio-prospecting or research project to which an application for a permit relates" and "traditional use or knowledge" as "the customary utilisation or knowledge of indigenous biological resources by an indigenous community, in accordance with written or unwritten rules, usages, customs or practices traditionally observed, accepted and recognised by them, and includes discoveries about the relevant indigenous biological resources by that community". Article 4(1) relates to Bioprospecting for discovery phase and commercialisation phase to be carried out by Bioprospecting Permit issued by Minister. For exporting indigenous biological resources, the applicant according to Article 4(2) must apply for an integrated export and bioprospecting permit to the Minister, who may issue a permit after complying to regulations mentioned by Article 4(3). Article 5 also allows for permit for research other for bioprospecting with an integrated export permit after complying with regulations by issuing authority.

6.4.23 Thailand and traditional Thai medicines Section 3 of Protection and Promotion of Traditional Thai Medicinal Intelligence Act, B.E. 2542 (1999) defines "Traditional Thai Medicine" as "the medicinal procedures concerned with examination, diagnosis, therapy, treatment or prevention or promotion and rehabilitation of the health of humans or animals, obstetrics, traditional Thai massage, and also includes the production of Traditional Thai drugs and the invention of medical devices on the basis of knowledge or text that has been passed from generation to generation." and defines "Texts on traditional Thai medicine" as "technical knowledge concerned with traditional Thai medicine which has been written or recorded in Thai books, palm leaf, stone inscription or other materials or that have not been recorded but passed on from generation to generation.". Further "Thai traditional drugs" is defined as "medicines obtained directly from herbs or derived from mixture, blended or transformed herbs, and also includes Thai traditional drugs under laws on drugs." Section 16 defines three types of traditional

Thai medicinal intellectual property rights, the national formula of Traditional Thai drugs or the national text on Traditional Thai Medicine; general formula of traditional Thai drugs or general traditional Thai medicine document; and; personal formula of traditional Thai drugs or personal text on traditional Thai medicine. Section 3 defines "right holder" as "those who have registered their intellectual property rights on traditional Thai medical intelligence under this Act". Section 14 defines Intellectual Property Rights on Thai Medicine as the right to intellectual property over the formula of traditional Thai drugs and text on traditional Thai medicine. Section 34 defines the rights of the right holder of traditional Thai drug as having "sole ownership on the production of the drug and have the sole right over the research, distribution, improvement or development of formulas on Traditional Thai drugs or intellectual property rights of traditional Thai medicine under the registered text on traditional Thai medicine."

6.4.24 Vanuatu and Indigenous Knowledge

Section 1 of Design Act No. 3 of 2003 defines "indigenous knowledge" as "any knowledge that is created, acquired or inspired for traditional economic, spiritual, ritual, narrative, decorative or recreational purposes; and whose nature or use has been transmitted from generation to generation; and that is regarded as pertaining to a particular indigenous person or people in Vanuatu." Section 62 defines scope of protection of designs involving indigenous knowledge to be referred to the National Council of Chiefs. Section 1 of Patents Act 2003 defines "indigenous knowledge" as defined by Section 1 of Design Act No 3 of 2003. Section 47 defines scope of protection of Registration of patents involving indigenous knowledge to be referred to the National Council of Chiefs.

6.4.25 Viet Nam, Traditional Knowledge and Genetic Resources Article 3 (28) of Biodiversity Law, No. 20/2008/QH12, 2009³³ defines Traditional knowledge of genetic resources as "knowledge, experience and initiatives of native people on the conservation and use of genetic resources." The Scope of protection is defined by Article 58 regarding to written Contracts on access to genetic resources and benefit

³³ Pursuant to the 1992 Constitution of the Socialist Republic of Vietnam, which was amended and supplemented under Resolution 51/2001/QH10 dated on December 25, 2001 of the Xth National Assembly, the 10th session; this Law stipulates biodiversity conservation and sustainable development.

sharing to be certified by commune-level People's Committees of localities where genetic resources are accessed containing the principal details like , sharing of benefits and distribution of intellectual property rights. Article 60 defines rights and obligations of organizations and individuals that are granted licenses for access to genetic resources to share benefits including the distribution of intellectual property rights over invention results based on their access to genetic resources and traditional knowledge copyrights on genetic resources. Article 64 defines Traditional knowledge copyrights on genetic resources to encourage support organizations and individuals to register traditional knowledge copyrights on genetic resources.

6.5 Legal Protection of Traditional Knowledge and Genetic Resources

6.5.1 *Sui-generis* protection of Traditional Knowledge and Genetic Resources for Andean Community

Article 3 of Decision No. 486 Establishing the Common Industrial Property Regime (2000) on scope of protection of biological and genetic heritage and traditional knowledge mandates member countries to ensure that the protection granted to intellectual property elements shall be accorded while safeguarding and respecting their biological and genetic heritage, together with the traditional knowledge of their indigenous, African American, or local communities. As a result, the granting of patents on inventions that have been developed on the basis of material obtained from that heritage or that knowledge shall be subordinated to the acquisition of that material in accordance with international, Andean Community, and national law. Article 26(i) On patent applications mentions applications for patents to be filed , if applicable may contain , "a copy of the document that certifies the license or authorization to use the traditional knowledge of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested was obtained or developed on the basis of the knowledge originating in any one of the Member Countries, pursuant to the provisions of Decision 391 and its effective amendments and regulations." According to Article 75 (h) the competent national authority may either ex officio or at the request of a party invalidate the patent null and void if the product or process has been developed on the basis of traditional knowledge if the applicant fails to submit a copy certifying lisencc or authorisation for use of that knowledge origination in any of the member countries.

6.5.2 Cuba and Access to Biological Material

Article 31.1 of Decree-Law No. 291 of November 20, 2011 on the Protection of Plant Varieties of Cuba mandates document indicating source of origin and source of the original plant material and associated traditional knowledge and practices to be submitted and a statement if the origin is not in Cuba has been obtained by consent to access

6.5.3 Egypt Disclosure for patent application

Article 3 of Council of Ministers Resolution No. 1366 of 2003 issuing Implementing regulations for Law No. 82 of 2002 on the Protection of Intellectual Property Rights Books One, Two and Four mentions trigger of Disclosure for patent application relating to an invention or utility model involving plant or animal biological material, traditional medicinal, agricultural, industrial or handicraft knowledge, or cultural or environmental heritage to be accompanied by documentation proving that the inventor has accessed the source from which the material was obtained in a legitimate manner, according to the legislation applicable in the Arab Republic of Egypt.

6.5.4 Philippines Biodiversity and Genetic Resource, Traditional Knowledge

Rule 12 of Implementing Rules and Regulations of Republic Act No. 10055 (Joint Administrative Order No. 02-2010) mentions under Section 3 *that* disclosure of potential IPRs and/or all biodiversity and genetic resource, traditional knowledge, and indigenous knowledge, systems and practices shall be sought with a written disclosure of patent containing any biodiversity, genetic resources or materials, associated traditional knowledge, and indigenous knowledge, systems and practices utilized in or which formed as basis in the development of the subject matter contained in the IPR application, with the primary source of any biodiversity, genetic resources or materials, associated traditional knowledge, and indigenous knowledge, systems and practices utilized in or which formed as basis in the subject matter contained in the IPR application or the secondary source, if no information about the primary source is available.

6.5.5 Switzerland Disclosure requirement and access

Article 49a of Federal Law of June 25, 1954 on Patents for Inventions (status as of January 1, 2012) mentions disclosure requirement that a patent application must contain information on the source of the genetic resource and of traditional knowledge of indigenous or local communities to which the inventor or the patent applicant had access, provided the invention is directly based on this resource. If the source is not known, it should be mentioned in the patent application confirmed in writing. Article 59 also mentions about setting a time limit for remedies if the patent application does not meet the requirements of the Act. Any person who willfully provides false information under Article 49a is liable to fine up to 100,000 francs according to Article 81a, with an additional publication of such judgment by court order.

6.5.6 South Africa Indigenous Biological Resource and Traditional Knowledge

Section 2 of Patents Amendment Act 2005 defines Genetic resource as any indigenous genetic material; or the genetic potential or characteristics of any indigenous species. Indigenous biological resource means an indigenous biological resource as defined in Section 1 of the National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004). Traditional knowledge means the knowledge that an indigenous community has regarding the use of an indigenous biological resource or a genetic resource. Subsection (3A) of Section 30 states "Every applicant who lodges an application for a patent accompanied by a complete specification shall, before acceptance of the application, lodge with the registrar a statement in the prescribed manner stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use. Section 61(1)(g) empowers any person at any time to file an application to revoke patent if the "declaration lodged in respect of the application for the patent or the statement lodged in terms of section 30(3A) contains a false statement or representation which is material and which the patentee knew or ought reasonably to have known to be false at the time when the declaration statement or representation was made."

6.6 Conclusions

Countries like Belgium, Denmark, Germany, China, Norway, Sweden, Italy, Cuba and Costa Rica have provided legal provisions for mentioning Disclosure of Origin of Genetic resource in Patent document particularly for biotechnological patents for geographical origin of biological material of plant or animal origin. Norway is a country that seeks Prior Informed Consent of genetic resource obtained. Such enabling provisions are ahead of TRIPS and CBD, where countries have used National laws to regulate unethical access and patent filing from genetic resource not obtained legally. Such redesign from existing minimum protection brings in a strategy to rethink governance issues with costs and benefits through access and benefit sharing for reducing complexities and redesigning policy framework by creatively addressing innovative solutions, through sui generis system, or regional collaboration or multilateral biodiplomacy