

ANNEX II


 COGNITIVE SUMMARY OF EXISTING NATIONAL SUI GENERIS MEASURES
AND LAWS FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE

1. The *sui generis* measures and laws analyzed in this document constitute a wide range of policy choices made by the countries with regard to the legal protection of TK. Since the information provided in Part 2 of the Annex is highly detailed and may not display the fundamental policy approaches of these measures in a simple format, Part 1 of the Annex summarizes the basic policy approaches which were taken by the national measures. These choices, and the considerations underlying them, are reflected in the Summary Table of Part 1 by describing the following aspects of the respective measures:

(a) most *sui generis* measures for TK combine two basic legal concepts to govern the use of TK: (1) the regulation of access to TK, and (2) the grant of exclusive rights for TK.¹ This combination reflects the two major legal frameworks within which most measures are adopted and implemented: intellectual property frameworks and access and benefit-sharing arrangements. In many cases, access regulation for TK is part of larger access and benefit-sharing frameworks which apply also to genetic or biological resources. The first row of the Summary Table therefore describes the basic legal and policy frameworks in which the measure was taken, including also, if relevant, unfair competition policy and indigenous rights;

(b) *sui generis* measures combine diverse conceptual and policy tools to customize legal protection for TK. These conceptual and policy tools include (1) the regulation of access to TK, (2) the grant of exclusive rights for TK, (3) concepts from the law on the repression of unfair competition and (4) references to customary laws of indigenous and local communities. The second row of the Summary Table thus describes these basic legal and policy tools that were utilized in the various laws and measures;

(c) most *sui generis* measures delimit the scope of subject matter which they cover through combinations of three criteria:

(i) sectorial distinctions: for example, traditional medicine,² traditional agriculture,³ etc. Some laws include distinct sets of rights for such sectoral areas. For example, the African Model Legislation provides for farmers' rights in the agricultural sector, in addition to community intellectual rights for all sectors;

(ii) association of the TK with tangible subject matter: for example, TK related to genetic resources,⁴ TK related to any properties of biological diversity,⁵ TK related to any aspects of ecosystems,⁶ etc.

¹ This is the case for seven out of ten measures described in the TK Panel and the Annex to the present document. See African Model Legislation of 2000; Provisional Measure No. 2186-16 of 2001 of Brazil; Law No. 7788 of 1998 on Biodiversity of Costa Rica; Biological Diversity Act of 2002 of India; Law No. 27,811 of 2002 of Peru; Indigenous Peoples' Rights Act of 1997 of the Philippines; and Decree Law No.118 of 2002 of Portugal.

² Thailand's Act on Protection and Promotion of Traditional Thai Medicinal Intelligence B.E 2542.

³ Portugal's Decree-Law No.118 of 2001.

⁴ Brazil's Provisional Measure N.2186-16 of August 23, 2001.

⁵ Peru's Law N. 27,811 of 2002.

(iii) association of TK with specific holders of knowledge: for example, indigenous peoples,⁷ members of ‘Indian tribes’ or Indian organizations,⁸ farming communities⁹, etc.

The choice of these criteria to delimit the protected subject matter is reflected in the third row of the Summary Table.

(d) most *sui generis* measures define the policy objectives which they aim to implement in respect of the protected subject matter. Numerous laws or measures on TK protection share certain policy objectives, such as the conservation of TK and associated biological diversity.¹⁰ These objectives are listed in the fourth row of the Summary Table;

(e) in some national contexts, different aspects of TK protection are being covered by distinct and complementary *sui generis* measures. In such cases, multiple measures have been entered in Part 2 of the Annex. The Summary Table in Part 1 reflects various forms of protection provided for TK in row five;

(f) numerous *sui generis* measures are linked to the legal regulation of access to, and use of, tangible subject matter which is associated with TK, such as genetic or biological resources. Row six of the Summary Table indicates whether there is such a linkage in each respective measure.

(g) an important part of these measures are the exceptions and limitations through which their application is circumscribed. These are listed in the final row of the Summary Table.

2. The description of these aspects in the tables of the Annex offers a comparative summary of existing measures and policy options that have been implemented by WIPO Member States at the national level. This detailed comparative information supplements documents WIPO/GRTKF/IC/5/7 and WIPO/GRTKF/IC/5/8 and may provide a substantive basis for future work foreseen in those documents.

3. The present document has been compiled using the texts of laws, related documents such as decrees and regulations, and, where relevant, information provided by Member States to the Committee at previous sessions. It should be noted that this material is provided as an information resource only, to assist the Committee’s discussions, and is not intended as an authoritative interpretation or legal assessment of any law or legal instrument. Several instruments referenced in this document are currently under revision¹¹ and the descriptions of certain instruments rely on unofficial translations.¹²

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Translators’ note: all this text is taken directly from document 5/INF/4

⁶ African Model Legislation (2000).

⁷ Peru’s Law N. 27,811 of 2002.

⁸ The Indian Arts and Crafts Act (1990) in the United States of America.

⁹ African Model Legislation (2000).

¹⁰ See the laws and measures of the African Union, Brazil, Costa Rica, India, Peru, Philippines and Portugal.

¹¹ For example, the Brazilian Provisional Measure No. 2186-16 of 2001 and the Chinese Regulation on Traditional Medicinal Species.

¹² For example, the Act on Protection and Promotion of Traditional Thai Medicinal Intelligence B.E 2542 of Thailand, or the Chinese Regulation on Traditional Medicinal Species.

Part 1

Summary Table
Regarding Policy Choices Reflected in
National Sui Generis Measures and Laws for
the Protection of Traditional Knowledge

This table summarizes the policy choices that are reflected in national and regional *sui generis* measures and laws for the protection of traditional knowledge. It includes references to the following *sui generis* laws and measures:

<i>African Union</i>	African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources of 2000;
<i>Brazil</i>	Provisional Measure No. 2186-16 of 2001 Regulating Access to the Genetic Heritage, Protection of and Access to Associated Traditional Knowledge;
<i>China</i>	The Patent Law of 2000 and the Regulations on the Protection of Varieties of Chinese Traditional Medicine;
<i>Costa Rica</i>	Law No. 7788 of 1998 on Biodiversity;
<i>India</i>	Biological Diversity Act of 2002;
<i>Peru</i>	Law No. 27,811 of 2002 Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources;
<i>Philippines</i>	Indigenous Peoples Rights Act of 1997;
<i>Portugal</i>	Decree Law No.118 of 2002 Establishing a Legal Regime of Registration, Conservation, Legal Custody and Transfer of Plant Endogenous Material;
<i>Thailand</i>	Act on Protection and Promotion of Traditional Thai Medicinal Intelligence, B.E 2542;
<i>United States of America</i>	Indian Arts and Crafts Act of 1990 and other relevant measures

		<i>African Model Law</i>	<i>Brazil</i>	<i>China</i>	<i>Costa Rica</i>	<i>India</i>	<i>Peru</i>	<i>Philippines</i>	<i>Portugal</i>	<i>Thailand</i>	<i>USA</i>
<i>Legal and Policy Framework</i>	<i>Intellectual property legislation</i>			√			√			√	√
	<i>Access and benefit-sharing frameworks</i>	√	√		√	√	√		√		
	<i>Indigenous rights</i>						√	√			
	<i>Repression of unfair competition</i>						√				√
<i>Policy tools utilized</i>	<i>Access regulation</i>	√	√		√	√	√	√	√		
	<i>Exclusive rights</i>	√	√	√	√			√	√	√	√
	<i>Repression of unfair Competition</i>				√		√		√		√
	<i>Customary law</i>	√					√	√			
<i>Scope of Subject Matter</i>	<i>- TK related to ...</i>	biological resources	Genetic heritage		Biological diversity	Biological resources	Biological resources		Landraces		
	<i>- Sectorial TK</i>	Traditional agriculture		Traditional medicine					Traditional Agriculture	Traditional medicine	
	<i>- TK held by ...</i>	Indig&local community	Indig&local community			local people	Indig&local community	ICCs/IPs			(members of) Indian tribes
<i>Policy Objectives</i>	<i>Conservation of TK (and other elements)</i>	√	√ (+genetic heritage)		√ (+biological diversity)	√ (+biological resources)	√		√ (+land-races)		√ (cultural heritage)
	<i>Innovation Promotion</i>			√			√		√		√
	<i>Fair and Equitable Benefit-sharing</i>	√ (+biological resources)	√ (+genetic heritage)		√ (+biological diversity)	√ (+biological resources)	√	√ (+biological resources)	√ (+land-races)		
	<i>(Sustainable) Development</i>	√					√	√			√
<i>Form of Protection</i>	<i>Positive</i>	√	√	√	√	√	√	√	√	√	√
	<i>Defensive</i>	√	√		√	√	√				√
	<i>Access regulation</i>	√	√		√	√	√	√	√		
<i>Regulation of associated tangible subject matter</i>	√	√	√	√	√			√	√	√	
<i>Exceptions and Limitations</i>	Customary use	Customary use		Customary use	Customary use	Customary use			Customary use	Customary use	

Part 2

Comparative Table
Regarding National and Regional *Sui Generis* Measures and Laws
for the Protection of Traditional Knowledge

This table compares the main provisions of the *sui generis* measures and laws listed on page 1 of the Annex with respect to the following fifteen elements that may be used to describe *sui generis* measures for TK protection:

- (1) Policy Objectives;
- (2) Scope of Protected Subject Matter;
- (3) Conditions of Access to Traditional Knowledge;
- (4) Conditions of Protection of Traditional Knowledge;
- (5) Scope of Rights;
- (6) Right Holder;
- (7) Acquisition of Rights;
- (8) Expiration and Loss of Rights;
- (9) Sanctions and Enforcement;
- (10) Registration Mechanisms and Other Procedures for the Acquisition and Maintenance of Rights;
- (11) Access and Benefit-sharing Elements (Mutually Agreed Terms and Prior Informed Consent);
- (12) Defensive Protection;
- (13) Regional and International Protection, Including the Problem of So-called “Regional Traditional Knowledge”;
- (14) Institutional Arrangements;
- (15) Recognition of Customary Laws and Protocols.

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	African Model Legislation	BRAZIL	CHINA	COSTA RICA	INDIA
1. Law/Measure	African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources (2000)	Provisional Measure N.2186-16 of August 23, 2001	Patent Law of the People's Republic of China of 2000 and Regulations on the Protection of Varieties of Chinese Traditional Medicine	Biodiversity Law No. 7788	Biological Diversity Act of 2002
2. Policy Objectives	<p>The main aim is to ensure the conservation, evaluation and sustainable use of the biological resources, and knowledge and technologies in order to maintain and improve their diversity. The specific objectives of the law include:</p> <ul style="list-style-type: none"> - to recognize, protect and support the inalienable rights of local communities, including farming communities, over their ... knowledge and technologies; - to recognize and protect the rights of breeders; - to provide an appropriate system for access to ... community knowledge and technologies; - to promote mechanisms for fair and equitable sharing of benefits arising from the use of ... knowledge and technologies; - to ensure the effective participation of concerned 	<p>To legislate on “(I) access to components of the genetic heritage ...; (II) access to traditional knowledge relating to the genetic heritage; (III) the fair and equitable sharing of the benefits deriving from exploitation of ... associated traditional knowledge; (IV) access to and transfer of technology for the conservation and use of biological diversity. (Art.1)</p>	<p><i>1. Patent Law of 2000:</i></p> <ul style="list-style-type: none"> - To accelerate the inventors' enthusiasm, and stimulate technology innovation; - To provide an important and effective means of traditional medicine intellectual property protection; <p><i>2. Regulations on the Protection of Varieties of Chinese Traditional Medicine:</i></p> <ul style="list-style-type: none"> - To improve product quality; - To normalize the market; - To wash out low quality medicine; 	<p>To regulate access and in so doing make possible the equitable distribution of the environmental, economic and social benefits to all sectors of society, paying special attention to local communities and indigenous peoples.</p> <ul style="list-style-type: none"> - to recognize and provide compensation for the knowledge, practices and innovations of indigenous peoples and local communities in the conservation and sustainable use ecological of the components of biodiversity. - to recognize the rights deriving from the contribution of scientific knowledge to the conservation and sustainable ecological use of the components of biodiversity. 	<p>to provide for conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources and knowledge</p>

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	PERU	PHILIPPINES	PORTUGAL	THAILAND	USA
1. Law/Measure	Law N. 27,811 of 2002	Indigenous Peoples Rights Act of 1997 (IPRA)	Decree-Law No.118, of April 20, 2002	Act on Protection and Promotion of Traditional Thai Medicinal Intelligence, B.E. 2542	(1) Indian Arts and Crafts Act (2000) (“IACA”); and (2) USPTO Database of Official Insignia of Native American Tribes, established as a result of the Trademark Law Treaty Implementation Act (1998)
2. Policy Objectives	<p>(a) To promote respect for and the protection, preservation, wider application and development of the collective knowledge of indigenous peoples;</p> <p>(b) To promote the fair and equitable distribution of the benefits derived from the use of that collective knowledge;</p> <p>(c) To promote the use of the knowledge for the benefit of the indigenous peoples and mankind in general;</p> <p>(d) To ensure that the use of the knowledge takes place with the prior informed consent of the indigenous peoples;</p> <p>(e) To promote the strengthening and development of the potential of the indigenous peoples and of the machinery traditionally used by them to share and distribute collectively</p>	<p>- To recognize, protect, and promote the rights of Indigenous Cultural Communities and Indigenous Peoples;</p> <p>- To provide for a system of community intellectual rights protection in respect of the innovative contribution of both local and indigenous cultural communities in the matter of development and conservation of genetic resources and biological diversities.</p>	<p>- To recognize, preserve and maintain the knowledge, innovations and practices of small farmers and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of plant agrobiodiversity and to promote their wider application with the involvement of the holders of such knowledge;</p> <p>- To stimulate and contribute to their conservation for coming generations as a part of the national heritage and the heritage of mankind;</p> <p>- To promote the conservation, legal safeguarding and transfer of autochthonous plant material of current or with potential interest to agrarian, agroforest and landscape</p>	No express provisions	<p>(1) <i>IACA</i>:</p> <p>- To promote the development of Indian arts and crafts and to create a board to assist therein, and for other purposes;</p> <p>(2) <i>Database of Official Insignia</i>:</p> <p>- To address issues surrounding the protection of the official insignia of federally and State recognized Native American tribes. (Section 302(a), Trademark Law Treaty Implementation Act)</p> <p>The legal protection provided in the United States is, in summary, intended:</p> <p>- To protect and preserve cultural heritage;</p> <p>- To prevent commercial interests from falsely associating their goods or</p>

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	African Model Legislation	BRAZIL	CHINA	COSTA RICA	INDIA
	<p>communities in deciding on the distribution of benefits deriving from ... knowledge and technologies;</p> <ul style="list-style-type: none"> - to encourage national and grassroots scientific and technological capacity; - to provide mechanisms for implementation and enforcement of rights of local communities and conditions of access to biological resources, community knowledge and technologies. (Part I) 			(Art.10(1), 10(6), 10(7))	
3. Scope of Subject Matter	<p>The scope of subject matter to which the legislation applies includes biological resources, their derivatives, “and community knowledge and technologies.” (Art.2(1)(i-iii))</p> <p>“Community knowledge” is defined as “the accumulated knowledge that is vital for conservation and sustainable use of biological resources and/or which is of socio-economic value, and which has been developed over the years in indigenous/local communities.” (Art.1)</p> <p>“Biological resources” are defined to include “genetic resources, organisms or parts thereof, populations, or any other component of ecosystems, including ecosystems themselves, with</p>	<p>Traditional knowledge of indigenous and local communities relating to the genetic heritage.</p> <p>“Associated traditional knowledge” is defined as: “information or individual or collective practices of an indigenous or local community having real or potential value and associated with the genetic heritage” (Art.7(II))</p>	<p><i>1. Patent Law of 2000:</i></p> <ul style="list-style-type: none"> - product, method, and use of medicines; - Product: a new pharmaceutical composition and preparation thereof, effective ingredient extracted/separated from traditional medicine, effective parts and preparation thereof, new preparation of changing the administration route, etc.; - Method: preparation method of the products mentioned above, new or improved technology of production, etc.; - Use: new indication of medicine, first medical use, the second use of the known medicine, etc. <p><i>2. Regulations on the</i></p>	<p>Two scopes of TK subject matter are defined in the Law: first, the scope of TK to which the Law regulates access, and, second, the scope of TK for which the Law provides exclusive rights (industrial property rights and sui generis community intellectual rights).</p> <p><i>Access to TK:</i></p> <p>The Law includes TK as an intangible component within in the term “biodiversity.” Art.2 defines that “intangible components, which are : the knowledge, innovations and practices, be they traditional, individual or collective, with real or</p>	<p>The Act foresees the protection of “knowledge of local people relating to biological diversity” (Art.36(5)). “Biological diversity” is defined as “the variability among living organisms from all sources and the ecological complexes of which they are a part, and includes diversity within species or between species and of eco-systems,” (Art.2(b))</p>

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	PERU	PHILIPPINES	PORTUGAL	THAILAND	USA
	generated benefits under the terms of the regime established by the law; (f) To avoid situations where patents are granted for inventions made or developed on the basis of collective knowledge of the indigenous peoples of Peru without any account being taken of that knowledge as prior art in the examination of the novelty and inventiveness of the said inventions. (Title V)		activity, including the local varieties and spontaneously occurring material (Preamble).		services with indigenous peoples.
3. Scope of Subject Matter	The Peruvian Law affords protection to “collective knowledge of Indigenous peoples that is connected with biological resources.” (Art.3) Protection is conferred to collective knowledge which is not in the public domain (Art.42). The term “collective knowledge” is defined as “the accumulated, transgenerational knowledge evolved by indigenous peoples and communities concerning the properties, uses and characteristics of biological diversity” (Art.2(b)). <i>Exceptions and limitations:</i> from the scope of protection include “the traditional exchange between indigenous peoples of the collective knowledge protected under	The subject matter which ICCs/IPs have the right to control, develop and protect includes “their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, including derivatives of these resources, traditional medicines and health 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 34) The subject matter that shall be protected by the	Traditional Knowledge is defined as comprising “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.” (Art.3(1)) 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	The scope of subject matter protected under the Act includes ‘formulas of traditional Thai drugs’ and ‘texts on traditional Thai medicine’ (Section 14). “Text on traditional Thai medicine” is defined as “the 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” (Section 3) “Formula of traditional Thai drugs” is defined as “a formula stated as the production process and ingredients which contain Thai traditional drugs, no	(1) IACA: The Implementing Regulations for the Act provide that, in general, the term “Indian product” means “any art or craft product made by an Indian.” (Section 309.2(d)(1)). The Regulations furthermore illustrate that Indian products include, but are not limited to: (i) Art works that are in a traditional or non-traditional Indian style or medium; (ii) Crafts that are in a traditional or non-traditional Indian style or medium; (iii) Handcrafts, i.e. objects created with the help of only such devices as allow the manual skill of the maker to condition

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	African Model Legislation	BRAZIL	CHINA	COSTA RICA	INDIA
	actual or potential use or value for humanity.” (Art.1)		Protection of Varieties of <i>Chinese Traditional Medicine</i> : - Limited to medicines produced only in China and without patent protection; - Limited to medicines categorized within the officially recognized classes	potential value associated with biochemical or genetic resources, whether these are protected or not by systems of intellectual property or by sui generis registration systems.” (Art.7.2) <i>Protection of TK:</i> The knowledge, practices and innovations of indigenous peoples and local communities related to the use of components of biodiversity and associated knowledge (Art.82)	

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	<p>this regime.” (Art.4)</p>	<p>State includes “the past, present and future manifestations of their [ICCs’/IPs’] cultures” (Section 32)</p>	<p>varieties and other spontaneously occurring autochthonous material covered by the Decree (Art.3). The material covered by the Decree includes “all local varieties and other spontaneously occurring autochthonous material of plant species that are of current or potential interest to agricultural, agroforest or landscape activity, ... with the exception of varieties protected by intellectual property rights.” (Art.2(1))</p>	<p>matter what form the ingredients are.” (Section 3). In general, “traditional Thai medicinal intelligence” means “the basic knowledge and capability concerned with traditional Thai medicine.” “Traditional Thai medicine” is defined as “the medicinal procedures concerned with examination, diagnosis, therapy, treatment or prevention of, 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 on from generation to generation.” (Section 3) According to Section 16, “there shall be three types of traditional Thai medicinal intellectual property rights as follows: (1) the national formula of traditional Thai drugs or the national text on traditional Thai Medicine;</p>	<p>the shape and design of each individual product. (Section 309.2(d)(2)) <i>Exeptions and limitations:</i> The Implementing Regulations exclude any art or craft products made before 1935 from the scope of application of the Act. (Section 309.2(d)(3), Implementing Regulations, dated October 21, 1996) <i>(2) Database of Official Insignia:</i> The term “Official insignia of Native American tribes” means the flag or coat of arms or other emblem or device of any federally or state-recognized Native American tribe, as adopted by tribal resolution and notified to the United States Patent and Trademark Office.</p>

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	African Model Legislation	BRAZIL	CHINA	COSTA RICA	INDIA
4. Conditions of Access to TK	<p>Access to TK is included in the regulation of access to biological resources. "Access" is defined as "the acquisition of ... community knowledge, innovations, technologies or practices as authorised by the National Competent Authority" (NCA) (Art.1)</p> <p>In the application for access to the NCA the applicant shall provide a description of the innovation, practice, knowledge or technology, associated with the biological resource and propose mechanisms for benefit-sharing (Art.4.(1)(xi) and 4(1)(x));</p> <p>Local communities have the right to refuse access to their TK where such access will be detrimental to the integrity of their natural or cultural heritage. (Art.19)</p> <p><i>Exceptions and limitations:</i> The legislation does not affect "access, use and exchange of</p>	<p>"Access to associated traditional knowledge" is defined as the "acquisition of information pertaining to knowledge or individual or collective practices, associated with the genetic heritage, of an indigenous or local community for purposes of scientific research, technological development or biological prospection, with a view to its application in industry or elsewhere" (Art.7 (V)).</p> <p>The Council can deliberate on "authorization of access to associated TK, subject to the prior consent of the owner." (Art. 11(IV)(b))</p> <p>The special authorization of access to associated TK for a national</p>	<p>No express provisions.</p>	<p>Access to TK is included in the regulation of access to biodiversity: "Access" is defined as "Action to obtain samples of components of Biodiversity ... or to obtain associated knowledge" (Art.7.1)</p> <p>The law recognizes the right of local communities and indigenous peoples to oppose access to their resources and associated knowledge (Art.66).</p> <p>The access policies proposed by the National Commission on the Management of Biodiversity will constitute the general rules for access and for the protection of intellectual rights concerning biodiversity. (Art.62)</p> <p>An access permit for research or bioprospecting does not grant nor delegate</p>	<p>The obtaining of any knowledge associated to biological resources occurring in India is subject to previous approval of the NBA for certain persons for purposes of research, commercial utilization, bio-survey or bio-utilization (Art.3 (1)).</p> <p>These provisions do not apply to collaborative research projects, which are approved by the Central Government and conform to its policy guidelines. (Art.5(1) and 5(3))</p> <p><i>Transfer of biological resources or knowledge:</i> No person who has been granted access shall transfer the biological resource or knowledge except with NBA permission (Art.20 (1)).</p> <p>Any person who intends to</p>

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				(2) the general formula of traditional Thai drugs or general traditional Thai medicine document; and (3) the personal formula of traditional Thai drugs or personal text on traditional Thai Medicine.” (Section 16)	
4. Conditions of Access to TK	The Law establishes different conditions of access to TK, depending on the purpose of access: (1) access for the purposes of commercial or industrial application, shall be subject to the signing of a license agreement in which terms are provided that ensure due reward for the said access and in which the equitable distribution of the benefits deriving therefrom is guaranteed (Art.7). A license contract for the use of collective knowledge is defined as “an express agreement concluded between the organization of indigenous peoples possessing collective knowledge and a third party that incorporates terms and conditions for the use of the said collective knowledge.” (Art.2(d)) For details on licensing contracts for collective knowledge see	Access to indigenous knowledge related to the conservation, utilization and enhancement of biological and genetic resources, shall be allowed within ancestral lands and domains of the ICCs/IPs only with a free and prior informed consent of such communities, obtained in accordance with customary laws of the concerned community (Section 35) “The State shall ... protect ... the right to the restitution of cultural, intellectual, religious, and spiritual property taken without their free and prior informed consent or in violation of their laws, traditions and customs.” (Section 32)	The provisions on Access to and Allocation of Benefits apply <i>mutatis mutandis</i> to traditional knowledge (Art.3(7)). Accordingly, access to traditional knowledge for purposes of study, research, improvement or biotechnological applications shall be subject to prior authorization by CoTeRGAPA, the owner of the registration having been heard. (Art.7(1)). Access as defined in Art.7(1) and 7(2) requires the fair allocation of the benefits resulting from such use, by prior agreement with the owner of the registration. (Art.7(4))	No express provisions.	No express provisions.

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	African Model Legislation	BRAZIL	CHINA	COSTA RICA	INDIA
	knowledge and technologies by and between local communities;" (Art.2(2)(ii))	<p>institution that carries on research and development activities in the biological and related fields, and for a national university, for a term of up to two years, renewable for equal periods, as provided in the regulations; (Art.11(IV)(d))</p> <p>Access to associated traditional knowledge, shall be had by collection of information respectively, and authorization shall only be given to a national research institution in the biological and related fields by prior authorization. (Art.16)</p> <p>Accredited institutions may be granted the powers to analyze applications for access to TK, subject to the PIC of the owners from the area (Art.14(I)(b));</p> <p>Access to TK associated with the national heritage shall be had by collection of information and authorization shall be given to a national institution that researches in the biological or related fields by prior</p>		rights (Art.71)	<p>transfer such resources or knowledge may apply to the NBA (Art.20 (2)).</p> <p>Local communities and <i>vaid</i>s and <i>hakim</i>s who practice indigenous medicine are not effected by a provision that citizens of India shall not obtain any biological resource for commercial utilization except after prior intimation to the State Biodiversity Board (Art.7)</p>

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	<p>'Mutually Agreed Terms' in the Section on 'Access and Benefit-sharing Elements' below.</p> <p>(2) As a general principle, those interested in having access to collective knowledge for the purposes of scientific, commercial and industrial application shall apply for the prior informed consent of the representative organizations of the indigenous peoples possessing collective knowledge (Art.6).</p>				

	African Model Legislation	BRAZIL	CHINA	COSTA RICA	INDIA
		authorization (Art.16)			
5. Conditions of Protection of TK	<p>Not specified.</p> <p>However, the duties of the NCA include to “identify the requirements ... necessary for the recognition of community intellectual rights and Farmers’ Rights.” (Art.58(iv)).</p> <p>Furthermore, Art.1 on Definitions requires that accumulated knowledge must be “vital for conservation and sustainable use of biological resources” and/or “of socio-economic value” and “developed over the years in indigenous/local communities” in order to constitute “community knowledge or indigenous knowledge” for the purposes of the Model Law (Art.1)</p>	<p>TK must be related to the genetic heritage, belong to an indigenous or local community, and have real or potential value. (Art.7.II and 8)</p> <p>Indigenous or local communities are guaranteed the rights granted under Art.9 on the condition that they created, developed, held or preserved the TK (Art.9).</p>	<p><i>1. Patent Law of 2000:</i></p> <ul style="list-style-type: none"> - novelty: examining according to the principle of complete identity of technical solution; - inventiveness: prominent substantive features and notable progress as compared with the existing technology <p>- practical applicability: product having medical effect; methods can be carried out or exploited industrially; use can be realized industrially;</p> <p><i>2. Regulations on the Protection of Varieties of Chinese Traditional Medicine:</i></p> <ul style="list-style-type: none"> - Limited to medicines which fulfill the official criteria. - No requirement of novelty, but should pass a quality inspection; 	<p>The requirements of sui generis community intellectual rights shall be determined by a participatory process with indigenous and small farmer communities to be defined by the National Commission for the Management of Biodiversity (Art. 83)</p>	<p>Knowledge must be related to biological diversity and held by local people (Art.36 (5)).</p>

	PERU	PHILIPPINES	PORTUGAL	THAILAND	USA
5. Conditions of Protection of TK	<p>The Law grants protection under several conditions:</p> <p>(1) <i>collective nature</i>: the knowledge must have been developed and preserved collectively (Art.2(b))</p> <p>(2) <i>related to biological diversity</i>: “Biological resources” is defined as “genetic resources, organisms or parts thereof, populations or any other kinds of biotic component of ecosystems that are of real or potential value or use to mankind.” (Art.2(e))</p> <p>(3) <i>developed by indigenous peoples</i>: “Indigenous peoples” means “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.” (Art.2(a))</p> <p>(4) <i>not in the public domain</i>: protection is only conferred to knowledge which is not in the public domain (Art.42). For the purposes of the law, collective knowledge is understood to be in the public domain when it has been made accessible to persons other</p>	No express provisions.	<p>Subject to different conditions, the Decree grants two levels of protection.</p> <p>1. All TK as defined in Art.3(1) shall be protected against reproduction or commercial or industrial use, subject to the following conditions:</p> <p>(a) the TK shall be identified, described and registered in the Register of PGR;</p> <p>(b) the description shall be so phrased that third parties may reproduce or utilize the TK. (Art.3(2)).</p> <p>2. TK may be afforded certain additional protection, subject to fulfilling either of the following conditions:</p> <p>(a) the TK has not been used in industrial activities, or</p> <p>(b) the TK is not publicly known outside the population or local community in which it originated (Art.3(4)).</p>	<p>The Thai Act does not include express provisions on conditions of protection, but the definitions in Section 3 contain certain conditions for traditional Thai medicine to be included in the scope of the Act. For example, the definition of the term “traditional Thai medicine” contains the qualification that the medicinal procedures, massage, production of traditional drugs or the invention of medical devices has to rest “<i>on the basis of knowledge or text that has been passed on from generation to generation.</i>” (Section 3). The definition of “text on traditional Thai medicine” states that the technical knowledge must, as a condition of inclusion under the definition, have been “passed on from generation to generation.” (Section 3).</p>	<p>(1) <i>IACA</i>: To be protected under the Act a product must meet the following requirements:</p> <ul style="list-style-type: none"> - it must be an “Indian product” as defined in the Act and the Implementing Regulations; - is must have been produced after 1935; - the producer of the concerned Indian product must be resident in the United States. <p>(2) <i>Database of Official Insignia</i>:</p> <ul style="list-style-type: none"> - if signs or symbols contain tribal names, recognizable likenesses of Native Americans or symbols perceived as being Native American in origin they are included in the database.

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6. Scope of Rights	<p>The scope of rights granted by the Model Legislation in relation to TK includes two categories of rights, namely community (intellectual) rights and farmers' rights.</p> <p><i>Community (Intellectual) Rights:</i> The Model Law recognizes the rights of communities over:</p> <ul style="list-style-type: none"> - their innovations, practices, knowledge and technologies acquired through generations; - the right to collectively benefit from the utilization of their innovations, practices, knowledge and technologies; - their rights to use their innovations, practices, knowledge and technologies in the conservation and sustainable use of biological diversity. (Art.16(iii)-(v)) <p>Local communities have the right to refuse access to their TK where such access will be detrimental to the integrity of their natural or cultural heritage. (Art.19)</p> <p>Exceptions and Limitations: No legal barriers shall be placed on the traditional exchange system of the local communities in the exercise of</p>	<p>Traditional knowledge associated to the genetic heritage is protected “against illicit use and exploitation and other actions that are harmful or have not been authorized” by the Management Council or an accredited institution (Art.8)</p> <p>Communities that create, develop, hold or preserve TK associated to the genetic heritage are guaranteed the right:</p> <p>(I) “to have the origin of the access to TK mentioned in all publications, uses, exploitation and disclosures”;</p> <p>(II) “to prevent unauthorized third parties from:</p> <ul style="list-style-type: none"> (a) using or carrying out tests, research or investigations relating to associated TK; (b) disclosing, broadcasting or re-broadcasting data or information that incorporate or constitute 	<p><i>Patent Law of 2000:</i></p> <ul style="list-style-type: none"> - the rights to prevent third parties not having the right holders' consent from making, using, offering for sale, selling or importing the patented invention; - bringing litigation when infringement occurs; <p><i>Regulations on the Protection of Varieties of Chinese Traditional Medicine:</i></p> <ul style="list-style-type: none"> - Limited to protect the production of the protected species; - Manufacturing without permission should be dealt with by the Health Department of local governments. 	<p>The scope of sui generis community intellectual rights shall be determined by a participatory process with indigenous and small farmer communities to be defined by the National Commission for the Management of Biodiversity (Art.83)</p>	<p>The Act maintains that the scope of rights granted by measures for protection, including <i>sui generis</i> systems, shall be “as recommended by the National Biodiversity Authority...” (Art.36(5))</p>

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	than the indigenous peoples by mass communication media such as publication or, when the uses or characteristics of a biological resource are concerned, where it has become extensively known outside the indigenous peoples. (Art.13)				
6. Scope of Rights	<p>Provided that the collective knowledge is not in the public domain, the protection granted is:</p> <p>(1) against the disclosure, acquisition or use of collective knowledge without the consent of the indigenous peoples and in an improper manner;</p> <p>(2) against unauthorized disclosure where a third party has legitimately had access to collective knowledge covered by a safeguard clause. (Art.42)</p> <p>Irrespective of whether collective knowledge is in the public domain or not, indigenous peoples have the rights of registering their collective knowledge (Title VI) and, in the event of access for purposes of commercial or industrial application, of licensing it (Art.7 and Title VII).</p>	<p>The scope of rights made available to ICCs/IPs includes:</p> <ul style="list-style-type: none"> - the right to practice and revitalize their own cultural traditions and customs (Section 32); - the right to the restitution of cultural, intellectual religious, and spiritual property taken without their free and prior informed consent or in violation of their laws, traditions and customs (Section 32). - the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations (Section 34). 	<p>The Law grants two different scopes of rights for different types of registered TK:</p> <p>Owners of registered TK which has not been industrially used or is not publicly known outside the originating local community shall have the right to:</p> <p>“(i) object to its direct or indirect reproduction, imitation and/or use by unauthorized third parties for commercial purposes; (ii) assign, transfer or license the rights in the traditional knowledge, including transfer by succession; (iii) exclude from protection any traditional knowledge that may be covered by specific industrial property registrations.” (Art.3(4))</p> <p>The owners of all other duly registered and described TK shall have the right to</p>	<p>The Act confers the right holder “the sole ownership on the production of the drug and 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” (Section 34). <i>Exceptions and limitations:</i></p> <p>“the provisions of paragraph one shall not apply to: (1) any act that is of benefit for studies, findings, tests or research according to the regulation specified by the Minister; or (2) preparation of specific drugs according to prescription of holders of registration certificate on traditional Thai medicine,</p>	<p><i>IACA:</i></p> <p>The Act prohibits the offering or displaying for sale or selling of any good, in a manner that falsely suggests it is Indian produced, an Indian product, or the product of a particular Indian or Indian tribe or Indian arts and crafts organization, resident within the United States (Section 104(a))</p> <p>The Board has the power to create Government trade marks of genuineness and quality for Indian products and the products of particular Indian tribes or groups (Section 2(g)). The scope of rights arising from the creation of such a mark is set out in the Trademark Act of 1946, as amended.<i>Database of Official Official Insignia:</i></p> <p>While the Database does</p>

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	<p>their rights (Art.21(2)) <i>Farmers' Rights</i> include the right to the protection of farmers' traditional knowledge relevant to plant and animal genetic resources. (Art.26(1)(a))</p> <p><i>Exceptions and Limitations:</i> - The legislation does not affect "access, use and exchange of knowledge and technologies by and between local communities;" (Art.2(2)(ii))</p>	<p>associated TK." (III) to "derive profit from economic exploitation by third parties of associated TK the rights in which are owned by the community." (Art.9) TK holders are allowed to license or assign their rights in TK. <i>Exceptions:</i> - TK protection "shall not affect, prejudice, or limit rights pertaining to intellectual property" (Art.8(IV)) - protection shall not impede "preservation, use and development of TK" (Art.8(III)) - customary uses by communities should be preserved in all cases (Art.4)</p>			
7. Right Holder	<p><i>Community (Intellectual) Rights:</i> Local and indigenous communities (Art.16, 17, 18, 19, 20, 21, 23). Art.23 specifies that "Community Intellectual Rights of the local communities, including traditional professional groups,</p>	<p>Indigenous and local communities (Art.8 and 9). "Local community" is defined as a "human group, distinguished by its cultural conditions, that traditionally organizes itself throughout successive</p>	<p><i>Regulations on the Protection of Varieties of Chinese Traditional Medicine:</i> Manufacturing enterprises only.</p>	<p>Who will be the title holder of sui generis community intellectual rights shall be determined by a participatory process with indigenous and small farmer communities to be defined by the National Commission for the</p>	<p>The Act does not define right holders, but defines the term "benefit claimers" to include "creators and holders of knowledge and information relating to the use of such biological resources, innovations and practices associated with</p>

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			protect the TK “against reproduction or commercial or industrial use” (Art.3(2)). Art. 3(3) confers on owners of TK the right to chooses to keep it confidential, “with the protection conferred by registration being limited to cases in which it is unfairly acquired by third parties.” (Art.3(3))	or (3) production of drugs for household use or production of drugs by state hospitals or government or state agencies, for use in state hospitals, or the use of text on traditional Thai medicine for benefits in treatment of patients in state hospitals, provided that it should be in accordance with the Rules issued by the Minister. Section 35 grants the possibility of transferring rights only by succession ¹³ . Section 36 allows the right holder to permit any person to use their right under Section 34. The second paragraph of Section 36 establishes “the permit for use of the right under paragraph one shall be in accordance with the rules, procedure and conditions prescribed in the Ministerial Regulation.”	not grant rights <i>per se</i> , it does provide registered tribes with evidence of the relationship between the tribe and their insignia, and could serve as a cause for denying an application for registration of a trademark.
7. Right Holder	The Peruvian Law identifies “indigenous peoples and communities” as the persons whose rights and power to dispose of their collective	Indigenous Cultural Communities and Indigenous Peoples (ICCs/IPs). ICCs/IPs are defined as “a group of	The owner of the rights can be any entity, whether public or private, Portuguese or from another country, individual or corporate that	Section 3 defines the term “right holder” as “those who have registered their intellectual property rights on traditional Thai medical	IACA: The term “Indian” is defined as “any individual who is a member of an Indian tribe; or for the

¹³ Section 35: “The intellectual property right on traditional Thai medicine under this section shall not be transferred to others, except for the case in which it is passed on by succession”

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	<p>Particularly traditional practitioners, shall at all times remain inalienable.” (Art.23(1)) “Local Community” is defined as “a human population in a distinct geographical area, with ownership over its biological resources, innovations, practices, knowledge, and technologies governed partially or completely by its own customs, traditions or laws”. (Art.1)</p> <p><i>Farmers’ Rights:</i> ‘Local farming communities’ (Art.24 (1) and 25) The term is not defined.</p>	<p>generations and through its own customs and preserves its social and economic institutions” (Art.7.III) Any associated traditional knowledge may be owned by the community, even if only one single member of the community holds that knowledge. (Art.9, Sole Paragraph)</p>		<p>Management of Biodiversity (Art.84 and 83)</p>	<p>such use and application” (Art.2(a))</p>

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	<p>knowledge are recognized (Art. 1). The indigenous peoples that possess collective knowledge related to biological resources are the holders of rights conferred by this regime (Art.42). The term “Indigenous peoples” is defined 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.” (Art. 2) Indigenous peoples shall be represented by their representative organizations for the purposes of this regime, due regard being had to the traditional forms of organization of the indigenous peoples (Art.14)</p>	<p>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... became historically differentiated from the majority of Filipinos.”(Section 3 (h)). Section 5 declares the community ownership of traditional resource rights (Section 5).</p>	<p>represents the interests of the geographical area in which the local variety is most widely found or where the spontaneously occurring autochthonous material displays the greatest interest for genetic variability. In the case of TK the owner must represent the interests of the region from where such knowledge is originated. (Art.9) The Preamble specifies that applicants for the legal registration of local varieties and spontaneously occurring autochthonous material “may be public or private bodies of any kind, such as self-supporting businesses, farmers’ associations, regional development associations or individuals.”</p>	<p>intelligence under this Act.” Right holders are national individuals and also, according to Section 43 of the Law, persons with the nationality of other nations who agree to permit persons with Thai nationality to have the protection of intellectual property rights protection on traditional Thai medicine. “The intellectual property right on traditional Thai medicine under this section shall not be transferred to others, except for the case in which it is passed on by succession.” (Section 35) The term “successor of formula on traditional Thai drugs or text on traditional Thai medicine” is defined in the Act as “persons who have been passed on with the text on traditional Thai medicine or formulas on traditional Thai drugs from the discoverer, the improver, or the developer of the substance, or those who have learnt from generation to generation from the discoverer, the improver or the developer of the substance, or those who were given the above</p>	<p>purposes of this section is certified as an Indian artisan by an Indian tribe.” (Section 6(d)(3)) The term “Indian tribe” means: “(A) any Indian tribe, band, nation, Alaska Native village, or other organized group or community which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians; or (B) any Indian group that has been formally recognized as an Indian tribe by a State legislature or by a State commission or similar organization legislatively vested with State tribal recognition authority.” (Section 6(d)(3)) The term “Indian arts and crafts organization” means any legally established arts and crafts marketing organization composed of members of Indian tribes. (Section 6(d)(4)). <i>Database of Official Insignia:</i> The beneficiaries of the Database are federally- and</p>

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8. Acquisition of Rights	Art. 58 includes among the duties of the National Competent Authority to “develop a system of registration of items protected by Community Intellectual Rights and Farmers’ Rights according to their customary practices and law.” (Art.58(vi)) However, non-registration of any TK is not to mean that it is not protected by Community Intellectual Rights (Art.23 (3)).	The Measure does not specify procedures or formalities for the acquisition of rights. Art. 11(II)(d) mentions the organization of a database containing information on associated TK by the Management Council, but there is no requirement for TK to be included in the database in order to be protected. Art. 8(II) mentions a cadastral record directed by the Management Council. (Art. 8(I))	<i>Patent Law of 2000:</i> Through filing an application for patent (Chapter III);	The <i>sui generis</i> community intellectual right “exists and is legally recognized by the mere existence of the cultural practice or knowledge related to genetic resources and biochemicals; it does not require prior declaration, explicit recognition nor official registration.” (Art.82)	The Act provides that measures to protect TK “may include registration of the knowledge at the local, State and national levels,” but does not expressly define registration as the required procedure for the acquisition of the legal protection foreseen in the Act.

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				mentioned from others.” (Section 3) The Act allows for joint ownership of IP rights in traditional Thai medicine (Section 32).	state-recognized tribes.
8. Acquisition of Rights	No formalities are required for the acquisition of rights.	No express provisions.	A condition for the acquisition of rights is that the TK “shall be identified, described and registered in the Register of Plant Genetic Resources (RRGV)”. (Art.3(2)(a)). The registration of the material confers on the owner thereof the right to a share in the benefits derived from its use. (Art.4(4)). Registered plant material must possess a designation and description that satisfy the conditions established by decree of the Minister of Agriculture, Rural and	Rights are acquired by applying for registration to the registrar in accordance with the rules, procedures and conditions prescribed in a Ministerial Regulation (Section 20). Section 24 establishes an examination of the application. If an application is not made in accordance with the Ministerial Regulation the applicant may be requested by the Registrar for changes within 30 days, and, if the applicant does not comply with the	<i>IACA:</i> The Board may create Government trademarks of genuineness and quality for Indian products and register them in the United States Patent and Trademark Office without charge (Section 2(g))

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			Fisheries.”(Art.4 (2)).	changes, the registration shall be revoked (Section 23). Registration functions on a first-to-file basis (Section 26). The procedure for registration involves an objection possibility by third parties (Section 29). If there is no objection, the the registrar shall issue an order authorizing the registration of IP rights on traditional Thai medicine to the applicant and the registration form shall be as prescribed in the Ministerial Regulation. The Director of the Institute for Traditional Thai Medicine shall be the central registrar and the provincial health chiefs are the provincial registrars. (Section 13) Section 22 includes two prohibitions for registration.	

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9. Expiration and Loss of Rights	<p><i>Community Intellectual Rights:</i> Art.23 specifies that “Community Intellectual Rights of the local communities, including traditional professional groups, particularly traditional practitioners, shall at all times remain inalienable.” (Art.23(1)) The publication of a written or oral description of TK, or its presence in a genebank or any other collection, or its local use, shall not preclude the local community from exercising its community intellectual rights in relation to those resources. (Art 23(4))</p>	No express provisions.	<p><i>Patent Law of 2000:</i> term of protection is limited to 20 years, counted from the date of filing the patent application; <i>Regulations on the Protection of Varieties of Chinese Traditional Medicine:</i> - Between 7 years and 30 years; - Protection can be renewed;</p>	No express provisions	No express provisions.
10. Sanctions and Enforcement	<p>The State shall establish appropriate agencies with the power to ensure compliance with the provisions of the Model Law (Art. 67.2). Sanctions and penalties may include: i) written warning; ii) fines; iii) automatic cancellation/ revocation of the permission for access; iv) confiscation of collected specimens; v) permanent ban from access to community knowledge and biological resources. 3) The violation committed shall be publicized and reported by the National</p>	<p>Economic exploitation of products or processes developed from TK that has been accessed not conforming to the Provisional Measure shall make the guilty part liable to payment of an indemnity equivalent to a minimum of 20% of the gross invoiced amount obtained through the marketing of the product or of royalties obtained from third parties as a result of the licensing of the product or process,</p>	<p><i>Regulations on the Protection of Varieties of Chinese Traditional Medicine:</i> - Manufacturing without permission should be dealt with by the Health Department of local governments.</p>	<p>Whoever carries out exploration, bioprospecting or has access to biodiversity without authorization from the Technical Office of the Commission ... will be imposed a fine varying between the equivalent of one and twelve salaries. (Art. 112) Civil Responsibility for damage caused to biodiversity is defined in the Organic Law of the Environment. (Art.110) Except the illicit situations</p>	<p>Whoever contravenes the provisions regarding Section 3 [Certain Persons Not to Undertake Biodiversity Related Activities Without Approval of NBA] or Section 4 [Results of Research Not To Be Transferred] or Section 6 [Applications for IP Rights Not to Be Made Without Approval of NBA] shall be punishable with imprisonment for a term which may extend to five years, or with fine which</p>

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9. Expiration and Loss of Rights	No express provisions.	No express provisions.	<p>The registration of TK shall be effective for a period of 50 years from the application therefore, and may be renewed for an identical period. (Art.3(6)).</p> <p>In the case of plant material registration shall be valid for a period of ten years and renewed for subsequent periods of the same duration, provided that the conditions required for the registration to be granted are maintained, on pain of termination. (Art.5)</p>	<p>The IP right on traditional Thai medicine shall be valid for a life time of the right holder of the registration and extend for another 50 years after his decease. (Section 33)</p> <p>In the case of joint ownership, the right extends for 50 years from the date won which the last joint owner deceased (Section 34)</p>	No express provisions.
10. Sanctions and Enforcement	<p>Indigenous peoples may bring infringement actions against whoever violates their rights under Art.42. An infringement action may also be brought when imminent danger exists that these rights may be violated. Infringement actions may also be brought <i>ex officio</i> by decision of INDECOPI (Art.43).</p> <p>Where an infringement of rights of indigenous peoples is alleged the burden of proof shall be on the defendant (Art.44).</p> <p>Indigenous peoples may also bring actions claiming</p>	<p>“When disputes involve ICCs/IPs, customary laws and practices shall be used to resolve the dispute.” (Section 65)</p> <p>“The NCIP, through its regional offices, shall have jurisdiction over all claims and disputes involving rights of ICCs/IPs: Provided, however, that no such dispute shall be brought to the NCIP unless the parties have exhausted all remedies provided under their customary laws. For this purpose, a</p>	<p>The use of registered plant material, plants or parts thereof, in a manner contrary to the rights conferred to the owner of the register, and specified in this law, and in the regulations under this Decree, as well as the infringement of the provisions of this legislation on traditional knowledge, constitute violations punishable with a fine of between €100 and €2,500. Negligence is punishable. In the event of responsibility for the violation resting with a corporate entity, the</p>	<p>The concerned party or the public prosecutor may file complaints with the court to revoke registration over IP rights on traditional Thai medicine that had been registered unfairly or contrary to Section 21 or Section 22. (Section 38)</p> <p>In case the person permitted with the IP right on traditional Thai medicine exercise their rights against public order or good morals or violate or do not comply with the conditions specified in the Ministerial Regulation</p>	<p>IACA: Within the United States, the IACA empowers the Indian Arts and Crafts Board (IACB), a federal agency, to refer violations to the Federal Bureau of Investigation. The IACB may independently recommend to the Attorney General of the United States that criminal proceedings be instituted. The IACB may also recommend that the Secretary of the Interior refer a matter to the Attorney General for civil</p>

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	<p>Competent Authority to the secretariats of relevant international agreements. 4) When the collector conducts his/her operations outside of national jurisdiction, any alleged violations by such a collector may be prosecuted through the cooperation of the government under whose jurisdiction the collector operates. Finally, decisions on agreements regarding access to community knowledge may be appealed through appropriate administrative channels. Recourse to the courts shall be allowed after exhaustion of all administrative remedies. (Art. 68)</p>	<p>whether or not protected by IP (Art. 26). Any act that contravenes the Provisional Measure shall be considered an administrative offense (Art. 30). Administrative offenses shall be punished with the following sanctions <i>inter alia</i>: I. a warning; II. a fine; III. Confiscation of products obtained on the basis of information relating to TK; IV. Confiscation of products derived from TK; V. Suspension of sales of the product derived from TK; VI. A ban on activities; VII. Prohibition of the activity; VIII-IX. Suspension or cancellation of registration, patent, license or authorization (Art.30§1). Art. 30, §4 establishes a minimum amount for the fines: “according to the gravity of the offense and as provided in the regulations, and may vary from R\$200 (two hundred reais) to R\$100,000 in the case of a natural person.” The</p>		<p>typified in the Biodiversity Law, penal responsibility will be that as prescribed in the Penal Code and special laws. To deal with offences committed by public officials in the exercising of their responsibilities, the legal authority could impose the penalty of special disqualification for a maximum up to five years. (Art.111) For the purposes of the Law, administrative faults and their correlative sanctions are understood as those established by the Organic Law of the Environment, the Law of Wildlife, Forest Law and in other applicable legislation. (Art.113)</p>	<p>may extend to ten lakh rupees and where the damage caused exceeds ten lakh rupees such fine may commensurate with the damage caused, or with both. (2) Whoever contravenes the provisions on Section 7 [Prior Intimation to State Biodiversity Board] or any order made under Section 24(2) [Power of State Biodiversity Board to Restrict Certain Activities] shall be punishable with imprisonment for a term which may extend to three years, or with fine which may extend to five lakh rupees, or with both. Section 56 regulates the penalty for contravention of directions or orders of Central government, State government, National Biodiversity Authority and State Biodiversity Boards. Section 57 regulates Offences by Companies. Every determination of benefit-sharing made by the NBA or a State Biodiversity Board under the Act or the order made by the High Court in any appeal ... shall ... be</p>

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	ownership and indemnification against the third party that uses their collective knowledge in a manner contrary to the provisions of the regime (Art.45). Title XI specifies procedures for bringing an infringement action (Art.47-62)	certification shall be issued by the Council of Elders/Leaders who participated in the attempt to settle the dispute that the same has not been resolved, which certification shall be a condition precedent to the filing of a petition with the NCIP.” (Section 66) “Decisions of the NCIP shall be appealable to the Court of Appeals by way of petition for review.” (Section 67) Furthermore, Chapter XI of the IPRA declares in Section 72 the Punishable Acts and Applicable Penalties and in Section 73, Persons Subject to Punishment.	maximum amount of fines shall be 30,000 euros. (Art.13) Art.14 establishes the accompanying sanctions.	issued under Section 36.2 or exercise their rights which may cause serious damage to an IP right on traditional Thai medicine that has been registered, the registrar shall have the power to revoke the permission to the IP rights on the traditional Thai medicine. The revocation of the permission to the IP right on traditional Thai medicine under this section shall be in accordance with the rules and procedure prescribed in the Ministerial Regulation.”	enforcement action. The criminal and civil penalties for violating the IACA are as follows: first time individual offenders are subject to fines of up to \$250,000 or five years’ imprisonment; businesses are subject to fines of up to \$1,000,000; subsequent violations expose individual offenders to fines of up to \$1,000,000 or fifteen years’ imprisonment, while business offenders face up to \$5,000,000 in fines.

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		minimum is different if the offense is committed by a legal entity or with its consent, (Art. 30§5: "...the fine shall be from R\$10,000 to R\$50,000,000, as determined by the competent authority, according to the gravity of the offense and as provided in the regulations.			deemed to be decree of the civil court and shall be executable in the same manner as a decree of that court. (Section 53)
11. Registration Mechanisms and Procedures	The Model Legislation establishes a National Information System which shall include "documentation of information on Community Intellectual Rights, Farmers' Rights, ... community innovations, practices, knowledge and technologies;" (Art.64 (1) and 65(1)). It further states that "[I] local communities may also establish databases on ... the knowledge and technologies of those communities." (Art.64 (2)). Access to information in the National Information System and the local databases shall be regulated by a charter setting out the rights of the owners of the data. (Art.64 (3)). Non-registration of any TK is not to mean that it is not	The Management Council shall establish criteria for the creation of a database for recording information on associated traditional knowledge; (Art.11(2)(d)) TK may be subject to a cadastral record, as directed by the Management Council or provided in specific legislation. (Art.8(II))	<i>Patent Law of 2000:</i> - The State Council shall register the certificate of patent for invention and announce it (Art.39)	An inventory will be made of specific sui generis community intellectual rights that communities ask to be protected. The recognition of these rights in the register is voluntary and free. The registration should be done unofficially and at the demand of the interested parties, without being subject to any formality. (Art.84) A register of rights of access, including to TK, will be organized by the Technical Office of the Commission. The registered information will be publicly available, except for trade secrets (Art.67 and 7.1)	The Act provides that measures to protect TK "may include registration of the knowledge at the local, State and national levels." (Art.36(5)). It further provides that "every local body shall constitute a Biodiversity Management Committee for conservation and documentation of biological diversity including ... the chronicling of knowledge relating to biological diversity." (Art.41(1));

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	PERU	PHILIPPINES	PORTUGAL	THAILAND	USA
11. Registration Mechanisms and Procedures	<p>The Law establishes three types of registers, which have the following purposes:</p> <p>(a) to preserve and safeguard the collective knowledge of indigenous peoples and their rights therein;</p> <p>(b) to provide INDECOPI with such information as enables it to defend the interests of indigenous peoples where their collective knowledge is concerned (Art.16).</p> <p>The collective knowledge of indigenous peoples may be entered in three types of register (Art.15):</p> <p>(a) <i>Public National Register of Collective Knowledge of Indigenous Peoples</i>: This register shall contain such collective knowledge as is in the public domain (Art.17). INDECOPI shall register the</p>	<p>No express provisions</p>	<p>The Law establishes the Register of Plant Genetic Resources (RRGV) and the National Directory of Registrations of Plant Genetic Resources (Art.4(1) and 4(6)).</p> <p>Registration in the RRGV is a condition for the acquisition of rights. (Art.3(2)(a)).</p> <p>The registration of the material confers on the owner thereof the right to a share in the benefits derived from its use. (Art.4(4)).</p>	<p>The Director of the Institute for Traditional Thai Medicine shall be the Central Registrar and the provincial health chiefs are the provincial registrars. (Section 13)</p> <p>Committee on Protection and Promotion of Traditional Thai Medicinal Intelligence shall lay down rules concerned with standards and procedures on registration of IP rights on traditional Thai medicine (Section 6(6)).</p> <p>The Institute for Traditional Thai Medicine under the Office of the Permanent Secretary, the Ministry of Public Health, having the authority to carry out duties concerned with protection [...] and shall also be responsible</p>	<p>(1) <i>IACA</i>: The Indian Arts and Crafts Board may register Government trademarks of genuineness and quality for Indian products in the USPTO without charge (Section 2(g))</p> <p>(2) <i>Database of Official Insignia</i>: In August 2001 the USPTO established a Database of Official Insignia of Native American Tribes. The database is for notice purposes, and relies on self-certification.</p>

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	African Model Legislation	BRAZIL	CHINA	COSTA RICA	INDIA
	protected by Community Intellectual Rights (Art.23 (3)). The duties of the NCA include to develop a system of registration of items protected by Community Intellectual Rights and Farmers' Rights and to standardise procedures (Art.58(vi) and (v))				

	PERU	PHILIPPINES	PORTUGAL	THAILAND	USA
	<p>collective knowledge as is in the public domain (Art.17), maintain this register (Art.15) and send the information entered in this register to the main patent offices in the world in order that it may be treated as prior art (Art.23).</p> <p>(b) <i>Confidential National Register of Collective Knowledge of Indigenous Peoples:</i> This register shall contain collective knowledge that is not in the public domain, shall be maintained by INDECOPI (Art.15), and may not be consulted by third parties (Art.18);</p> <p>(c) <i>Local Registers of Collective Knowledge of Indigenous Peoples:</i> Indigenous peoples may organize local registers in accordance with their practices and customs and, upon request, INDECOPI shall lend technical assistance in the organization of such registers (Art.24). Applications for registration shall contain: (a) identity of the indigenous people applying for registration; (b) identity of the representative; (c) designation of the</p>			<p>for the administrative and technical works of the Committee. (Section 12)</p>	

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	African Model Legislation	BRAZIL	CHINA	COSTA RICA	INDIA
12. Access and Benefit-sharing Elements (Mutually Agreed Terms and PIC)	<p><i>PIC:</i> Any access to TK shall be subject to the necessary PIC of the National Competent Authority (NCA) as well as concerned local communities (Art.3(1), 5(1) and 18).</p> <p>All access applications shall be submitted to the National Competent Authority (NCA) and the NCA shall subject them to the PIC of the concerned community (Art.3 (3) and 11(1)). Any access granted without consultation with the local communities shall be deemed to be invalid and in violation of the PIC requirement (Art.5 (3)). The granting of access, including to TK, shall be</p>	<p><i>PIC:</i> Authorization of Access to TK shall be granted with the prior consent of:</p> <p>I. the indigenous community involved;</p> <p>II. the competent body where access occurs in a protected area;</p> <p>III. the owner where access occurs on private land; (Art.16§9)</p> <p>When there is a prospect of commercial use, <i>in situ</i> access to associated traditional knowledge may only occur after the Contract for Use of the Genetic Heritage and Benefit-Sharing has been signed (Art.16§4).</p>	No express provisions.	<p><i>PIC:</i> The basic requirements for access include (1) PIC of the representatives of the place where the access will occur; (2) Approval of PIC by the Technical Office of the Commission; (3) the terms of technology transfer and distribution of benefits, where there are any, and the type of protection of TK (Art.63 (1)-(3)).</p> <p>In relation to an application for whichever type of access to components of biodiversity, including TK, interested parties should attach the prior informed</p>	<p><i>PIC:</i> Certain persons shall not obtain any knowledge associated to biological resources occurring in India for research or for commercial utilization or for bio-survey and bio-utilization without previous approval of the NBA (Art.3(1))</p> <p><i>Mutually agreed terms:</i> The term “benefit-claimers” is defined to include “creators and holders of knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application;”</p>

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	<p>biological resource to which the collective knowledge relates, it being possible to use the indigenous name; (d) a mention of the use(s) that are made of the biological resource concerned; (e) a clear and full description of the collective knowledge to be registered; (f) the instrument embodying the agreement of the indigenous people to the registration of the knowledge (Art.20)</p> <p>INDECOPI may at any time cancel a registration or a license, after hearing the parties concerned, where:</p> <p>(a) the registration or license was granted in violation of any of the regime established by the Law;</p> <p>(b) it is shown that the data in the application are false or inaccurate (Art.34).</p>				
12. Access and Benefit-sharing Elements (Mutually Agreed Terms and PIC)	<p><i>PIC:</i> Those interested in having access to collective knowledge for the purposes of scientific, commercial and industrial application shall apply for the prior informed consent of the representative organizations of the indigenous peoples possessing collective knowledge. The organization of the indigenous peoples shall inform the</p>	<p><i>PIC:</i> Access to indigenous knowledge related to biological resources, within ancestral lands and domains is subject to PIC of ICCs/IPs (Section 35). PIC is defined as “the consensus of all members of the ICCs/IPs to be determined in accordance with their</p>	<p><i>PIC:</i> Access to traditional knowledge for purposes of study, research, improvement or biotechnological applications shall be subject to prior authorization by CoTeRGAPA, the owner of the registration having been heard. (Art.7(1)).</p> <p><i>Mutually Agreed Terms:</i> Access as defined in</p>	No express provisions.	No express provisions.

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	African Model Legislation	BRAZIL	CHINA	COSTA RICA	INDIA
	<p>carried out by the NCA in writing and carried out through a written agreement (“the Agreement”) between the NCA and local community on the one hand and the applicant on the other (Art.7)</p> <p>The Agreement referred to in Art.7 shall contain a commitment by the collector not to apply for any IP rights over the biological resource and over the TK without the PIC of the providers (Art.8 (1)(v)).</p> <p><i>Mutually Agreed Terms:</i> The Agreement referred to in Art.7 shall contain a commitment by the collector to provide for sharing of benefits (Art.8(1)(vi))</p> <p>The access permit should be subject to payment and the State and the community shall be entitled to a share of the earning derived from when any knowledge collected generates, directly or indirectly, a product used in a production process. (Art.12)</p> <p>The State shall ensure that at least fifty per cent of benefits provided for in Article 12.2 shall be channelled to the concerned local community, with the full participation and approval of the concerned local</p>	<p>Essential clauses of the Contract relate to IP rights (Art.28.V)</p> <p><i>Mutually Agreed Terms:</i> The benefits arising from economic exploitation of a product or process developed from associated TK, shall be shared in a fair and equitable way between the contracting parties. (Art.24)</p> <p>The institution receiving associated TK shall facilitate transfer of technology for the preservation and use of that TK for the national institution responsible for access and dispatch of the TK (Art.21)</p>		<p>consent, given by the proprietor of the landed estate where the activity will take place or by the authority of the indigenous community when it is in their territories. (Art.65)</p> <p><i>Mutually agreed terms:</i> The basic requirements for access to TK as a component of biodiversity include “the terms of technology transfer and equitable distribution of benefits, when there are any, as agreed in permits, agreements and concessions, as well as the type of protection of associated knowledge demanded by the representatives of the place where the access will occur.” (Art.63(3)).</p> <p>The Technical Office will establish the obligation of the interested party to deposit up to 10% of the research budget and up to 50% of the bonuses which it collects, in favour of the National System of Conservation Areas, the indigenous territory or the private owner providing access. Moreover, it will determine the amount which in each case should</p>	<p>(Art.2 (a)); While granting access approvals, NBA shall secure benefit-sharing for innovations and practices associated with the use of accessed biological resources and knowledge related thereto in accordance with mutually agreed terms between the access applicant, the local bodies concerned and the benefit claimers. (Art.21 (1)).</p> <p>The benefit-sharing can be given effect, <i>inter alia</i>, through grant of joint ownership of IP rights to the NBA or benefit claimers where applicable (Art.21(2)(a))</p> <p>Where any amount of money is ordered by way of benefit sharing, the NBA may direct the amount to be deposited in the National Biodiversity Fund. Provided that where knowledge was a result of access from specific individual or group, the NBA may direct that the amount shall be paid directly to such individual or group of individuals. (Art.21(3))</p>

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	<p>greatest possible number of indigenous peoples possessing the knowledge that it is engaging in negotiations and shall take due account of their interests and concerns, in particular those connected with their spiritual values or religious beliefs. The information supplied shall be confined to the biological resource to which the collective knowledge under negotiation relates in order to safeguard the other party's interest in keeping the details of the negotiation secret. (Art.6)</p> <p><i>Mutually Agreed Terms:</i> If access is sought for commercial or industrial application, a license agreement shall be signed in which the equitable distribution of the benefits deriving from the access is guaranteed (Art.7) A license contract is defined as "an express agreement concluded between the organization of indigenous peoples possessing collective knowledge and a third party that incorporates terms and conditions for the use of the said collective knowledge." (Art.2(d)) Additional conditions that</p>	<p>respective customary laws and practices, free from any external manipulation, interference coercion, and obtained after fully disclosing the intent and scope of the activity, in a language and process understandable to the community." (Section 3(g))</p>	<p>Art.7(1) and 7(2) requires the fair allocation of the benefits resulting from such use, by prior agreement with the owner of the registration. (Art.7(4)) The registration of the material referred to in paragraph 4(1) confers on the owner thereof the right to a share of the benefits derived from its use (Art.4(4)).</p>		

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	community (Art.22)			be paid by the interested parties for administrative costs, as well as any other benefit or technology transfer which forms part of the PIC. (Art.76)	

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	<p>apply to license contracts include that:</p> <ul style="list-style-type: none"> - License contracts shall be written and for a renewable period between one and three years (Art.26);. - License contracts shall be recorded in the Register of licenses. - License contracts shall contain certain clauses, such as: <ul style="list-style-type: none"> ▪ A statement of the compensation that the indigenous peoples will receive for the use of their collective knowledge, which shall include: (i) an initial monetary payment or an equivalent for its sustainable development, and (ii) a percentage of not less than 5% of the value, before taxes, of the gross sales resulting of the marketing of the products developed from the said collective knowledge. ▪ The provision of sufficient information on the purposes, risks and implications of the said activity, including any uses of the knoweldge;. 				

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	PERU	PHILIPPINES	PORTUGAL	THAILAND	USA
	<ul style="list-style-type: none"> ▪ The obligation of the licensee to inform the licensor periodically, in general terms, of progress on research, and on industrialization and marketing of the products developed from the licensed collective knowledge. <p>The licensing of the collective knowledge shall not prevent other indigenous peoples from using or licensing the same knowledge, nor shall it affect the right of present and future generations to continue to use and develop collective knowledge (Art.32).</p> <p><i>Benefit-sharing:</i> Indigenous peoples may obtain benefits from their collective knowledge in two ways:</p> <p>(1) Directly: through payment in two stages pursuant to license contracts;</p> <p>(2) Indirectly through the Fund for the Development of Indigenous Peoples:</p> <p>The purpose of the Fund is to contribute to the development of indigenous peoples through the financing of projects and other activities (Art.37). The Fund was created to allow all indigenous peoples – regardless of their</p>				

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	African Model Legislation	BRAZIL	CHINA	COSTA RICA	INDIA
13. Defensive Protection	<p>The access agreement referred to in Art.7 shall contain a commitment by the collector not to apply for any IP rights over the biological resource and over the TK without the PIC of the providers (Art.8 (1)(v)).</p> <p>The activities of the National Information system shall include “the compilation of information on piracy of” TK, and “the disseminating of this information to all relevant and concerned bodies.” (Art.65(iii))</p>	<p>The grant of industrial property rights for a process or product obtained using the genetic heritage is contingent on the observance of this Provisional Measure.</p> <p>The applicant is obliged to specify the origin of the genetic material and the associated TK, as the case may be. (Art.31)</p>	<p><i>Patent Law of 2000:</i></p> <p>The use of advanced search tools for patent and non-patent literature during substantive examination of TK-related patent applications, for example the China TCM Patent Database.</p>	<p>Patents, trade secrets, plant breeders’ rights, sui generis community intellectual rights and farmers’ rights shall not apply to inventions essentially derived from knowledge which is associated with traditional or cultural biological Practices in the public domain (Art.78)</p> <p>The registration of TK in the register will oblige the Technical Office [of the National Commission for the Management of Biodiversity] to respond negatively to any Consultation concerning the recognition of intellectual or industrial rights over the same component or knowledge. Such rejection must always</p>	<p>The NBA may take any measures necessary to oppose the grant of IP 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. (Art.18(4))</p> <p>No invention based on any information on a biological resource obtained from India shall be the subject of any application for any IP right without previous approval of NBA before making such application. (Art.6) Persons intending to apply for IP rights over such subject matter may make an application to the NBA (Art.19(2))</p>

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	<p>participation in a license contract - to enjoy the benefits derived from the use of their collective knowledge.</p> <p>A percentage of no less than 10% of the value of the gross sales resulting of the marketing of the products developed from a collective knowledge shall be set aside for the Fund (Art.8). If the collective knowledge has passed into the public domain in the last 20 years, an unspecified percentage of the value of the gross sales resulting of the marketing of the products developed from this knowledge shall be set aside for the Fund (Art.13).</p>				
13. Defensive Protection	<p>The Law has the objective to avoid situations where patents are granted for inventions made on the basis of collective knowledge of the indigenous peoples of Peru without any account being taken of that knowledge as prior art in the examination of the novelty and inventiveness of the said inventions (Art.5(f))</p> <p>With a view to its opposing pending patent applications, disputing granted patents or otherwise intervening in the grant of patents for inventions developed on the basis of</p>	No express provisions.	No express provisions.	No express provisions.	<p><i>Database of Official Insignia:</i></p> <p>All trademark applications containing tribal names, recognizable likenesses of Native Americans, symbols perceived as being Native American in origin, and any other application that the USPTO believes suggests an association with Native Americans, are examined with reference to the Database by one attorney who has developed expertise and familiarity in</p>

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				be properly justified. (Art.84)	
14. Regional and International Protection, including the Problem of So-called “Regional TK”	No express provisions. When the collector conducts his/her operations outside of national jurisdiction, any alleged violations by such a collector may be prosecuted through the cooperation of the government under whose jurisdiction the collector operates based on the guarantee that the latter has provided (Art.67 (4)).	No express provisions.	No express provisions.	No express provisions. However, the objectives of the law include “to promote international and regional co-operation to achieve the ... distribution of benefits derived from biodiversity [including TK], especially in frontier areas or from shared resources. » (Art.10(11)) Art.12 on International Co-operation provides that “The State should promote national activities, foreign relations and co-operation with national Neighbours with respect to the conservation, use and exchange of components of biodiversity [including TK] present in the national territory and in the transfrontier ecosystems of common interest.” (Art.12)	No express provisions.
15. Institutional Arrangements: Responsibilities of National Competent Authorities	The duties of the National Competent Authority include to: i) create and operate a regulatory mechanism that will ensure effective protection of Community	The competencies of the Management Council shall include to: II. Establish : (a) technical standards, (b) criteria for authorization of access	<i>Patent Law of 2000:</i> The patent administration department under the State Council is responsible for the patent work throughout the country. It receives and	Art. 13 establishes the administrative organization in order to fulfill the objectives of the law: a) the National Commission for the Management of	Article 8(1) establishes the National Biodiversity Authority (NBA). The head office of the NBA shall be at Chennai and the NBA may establish

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	collective knowledge, INDECOPI shall send the information entered in the Public National Register to the main patent offices of the world in order that it may be treated as prior art in the examination of the novelty and inventiveness of patent applications. (Art.23)				this area. The USPTO may refuse statutorily a proposed mark which falsely suggests a connection with an indigenous tribe or beliefs held by that tribe. The Database may thus prevent the registration of a mark confusingly similar to an official insignia.
14. Regional and International Protection, including the Problem of So-called 'Regional TK'	No express provisions.	No express provisions.	No express provisions.	No express provisions.	No express provisions.
15. Institutional Arrangements: Responsibilities of National Competent Authorities	INDECOPI shall be competent to settle in the first instance all matters concerning the protection of the collective knowledge of	The National Commission on Indigenous Peoples (NCIP) is the primary government agency,	The Register of Plant Genetic Resources (RRGV) is created in the General Directorate of Crops Protection, belonging to the	The Act establishes the Committee on Protection and Promotion of Traditional Thai Medicinal Intelligence. The Director	<i>IACA:</i> The Indian Arts and Crafts Board was established in 1935. It operates as an agency within the

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	Intellectual Rights and Farmers' Rights; ii) carry out the process of consultation and participation of local communities, including farming communities, in the identification of their rights as provided for under the customary practices and laws of the communities; iii) identify types of Community Intellectual Rights and Farmers' Rights; iv) identify and define the requirements and procedures necessary for the recognition of Community Intellectual Rights and Farmers' Rights; v) develop criteria and mechanisms to standardize procedures; vi) develop a registration system of items protected by Community Intellectual Rights and Farmers' Rights; vii) issue licenses for the exploitation and commercialization of TK; viii) identify relevant technical institutions that will assist local communities, including farming communities, in the categorization and characterization of their TK. (Art.58)	and dispatch; (c) directives for drafting the Contract for Use of the Genetic Heritage and Benefit-Sharing; (d) criteria for the creation of a database for recording information on associated TK; III. Take part in the work of accessing associated TK; IV. Deliberate on: (b) authorization of access to traditional knowledge, subject to the prior consent of the owner; [...] (Art.11)	examines patent applications and grants patent rights for inventions-creations in accordance with law. The administrative authority for patent affairs under governments of provinces, autonomous regions and municipalities directly under the Central Government are responsible for the administrative work concerning patents in their respective administrative areas. (Art.3)	Biodiversity (NCMB); b) a National System of Conservation Areas. The NCMB has the function to formulate and co-ordinate policies for access to biodiversity and associated knowledge. The NCMB Technical Office has the function to negotiate and approve access applications, and to co-ordinate anything related to access with the private sector, indigenous peoples and peasant communities. (Art.14 and 17) The membership of the NCMB is regulated in Art. 15 and the organization and internal structure in Art.16.	officers at other places in India. Section 9 regulates the Conditions of Service of the NBA Chairperson and members, Section 12 the Meetings of the NBA, and Section 13 the Committees of the NBA. It shall be the duty of the NBA to issue guidelines for access to biological resources and for fair and equitable benefit sharing. The NBA may grant approval for undertaking any activity referred to in sections 3, 4 and 6. Chapter VI regulates the establishment of State Biodiversity Board by the State Government (Section 22); the functions of State Biodiversity Board (Section 23) and the Power of State Biodiversity Board to restrict certain activities (Section 24).
16. Recognition of customary laws and protocols	The State recognises and protects the community rights that are specified in Article 16 “	No express references to customary laws.	No express references to customary laws.	No express references to customary laws.	No express references to customary laws.

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	<p>indigenous peoples. The Intellectual Property Chamber of the Tribunal for the Defense of Competition and Intellectual Property of INDECOPI shall settle all appeals in the second and last administrative instance. (Art.63)</p> <p>The Law establishes the Indigenous Knowledge Protection Board with five members and the responsibility of monitoring and overseeing the implementation of the Law (Art.65 and 66).</p>	<p>located under the Office of the President, which is responsible for the formulation and implementation of policies, plans and programs to recognize, protect and promote the rights of ICCs/IPs (Section 3(k) and Chapter VII);</p>	<p>Ministry of Agriculture, Fisheries and Rural Development. (Art.4(1)). Other official entities will be need to collaborate in this process, namely Institutions from the Ministry of Environment, Regional Agricultural Services and Municipal Chambers (Art.9)</p>	<p>of the Institute for Traditional Thai Medicine shall be a member and secretary of the Committee (Section 5).</p> <p>The Act also establishes the Institute for Traditional Thai Medicine under the Ministry of Public Health, having the authority to carry out duties concerned with protection and promotion of intelligence on traditional Thai medicine and herbs. The Institute shall also be responsible for the administrative and technical work of the Committee. (Section 12)</p>	<p>Department of the Interior and administers the Indian Arts and Crafts Act. The Board interprets potentially unlawful conduct for enforcement purposes. It can, for example, refer complaints of criminal violations to the Federal Bureau of Investigation and recommend to U.S. Attorney General that criminal proceedings be instituted.</p> <p><i>Database of Official Insignia:</i> The Database of Official Insignia of Native American Tribes is maintained by the USPTO.</p>
16. Recognition of customary laws and protocols	<p>Customary laws and protocols are referred to in several provisions of the Law:</p> <ul style="list-style-type: none"> - This regime shall not affect the traditional exchange between indigenous peoples of 	<p>The State ... shall recognize the applicability of customary laws governing property rights or relations in</p>	<p>No express provisions.</p>	<p>No express provisions.</p>	<p>No express provisions.</p>

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	<p>“as they are enshrined and protected under the norms, practices and customary law found in, and recognised by, the concerned local and indigenous communities, whether such law is written or not” (Art.17)</p> <p>An item of TK shall be identified, interpreted and ascertained by the local communities concerned themselves under their customary practice and law, whether such law is written or not. (Art.23(2))</p> <p>Local communities shall exercise their inalienable right to access, use, exchange or share their biological resources as regulated by their customary practices and laws (Art.21(1))</p> <p>“Local communities” are defined as “a human population ... with ownership over its ... knowledge, ... <i>governed partially or completely by its own customs, traditions or laws.</i>” (Art.1)</p> <p>“Local communities shall exercise their inalienable right to ... exchange ... their biological resources ... as regulated by their customary practices and laws.” (Art.21(1))</p>				

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	<p>the collective knowledge (Art.4). The rights granted under the regime shall be independent of those that may come into being within the indigenous peoples, who may use their traditional systems of distribution of benefits (Art.10). Indigenous peoples shall be represented by their representative organizations, due regard being had to the traditional forms of organization of the indigenous peoples (Art.14). Indigenous peoples may organize local registers in accordance with their practices and customs (Art.24). To the extent possible, the Administrative Committee of the Fund shall use the mechanisms traditionally used – by indigenous peoples - for sharing and distributing collectively generated benefits (Art.39). To settle the disputes that may arise between indigenous peoples in connection with the implementation of this regime ... indigenous peoples may use their customary law and their traditional forms of dispute settlement (Art.46).</p>	<p>determining the ownership and extent of ancestral domain (Section 2(b)); The term “customary law” is defined as “a body of written and/or unwritten rules, usages, customs and practices traditionally and continually recognized, accepted and observed by respective ICCs/IPs” (Section 3(f)); The ICCs/IPs shall have the right to use their own commonly accepted justice systems, conflict resolution institutions, peace building processes or mechanisms and other customary laws and practices within their respective communities and as may be compatible with the national legal system and with internationally recognized human rights (Section 15) Access to indigenous knowledge related to the conservation, utilization and enhancement of biological resources, shall be allowed within</p>			

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	<p>“No legal barriers shall be placed ... in other rights that may be provided by the customary practices and laws of the concerned local communities.” (Art.21(2))</p> <p>“Farmers’ varieties and breeds ... shall be protected under the rules of practice as found in, and recognised by, the customary practices and laws of the concerned local farming communities, whether such laws are written or not.” (Art.25(1))</p> <p>The duties of the NCA include to “carry out the process of consultation ... of local communities, including farming communities, in the identification of their rights as provided for under the customary practices and laws of the communities” (Art.58(ii))</p>				

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		<p>ancestral lands and domains of the ICCs/IPs only with a free and prior informed consent of such communities, obtained in accordance with customary laws of the concerned community. (Section 35)</p> <p>The provision on application of laws states that “Customary laws, traditions and practices of the ICCs/IPs of the land where the conflict arises shall be applied first with respect to property rights, claims and ownerships, hereditary succession and settlement of land disputes. Any doubt or ambiguity in the application and interpretation of laws shall be resolved in favor of the ICCs/IPs.” (Section 63)</p>			

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