Disclosure Requirements Table

This table comprises a non-exhaustive selection of extracts from existing legislative texts which, in one way or another, provide for a specific disclosure requirement related to genetic resources and/or traditional knowledge. The extracts are taken directly from the legislative texts as contained in WIPO's global database, WIPO Lex. The table contains no interpretation or commentary. In order to facilitate the reading and comprehension of the table, some relevant parts of the extracts may appear in bold, but this highlighting does not appear in the original legislative texts. All information provided is for information purposes only, and is not a substitute for legal advice. The WIPO Secretariat makes every effort to ensure, but cannot guarantee, the accuracy of the data contained in this selection. In particular, WIPO assumes no responsibility for any discrepancy that may occur in the electronic manipulation of the said data. The WIPO Secretariat will continue to add to and update the table over time. Additional contributions to the table, and any corrections and comments, would be appreciated and may be sent to grtkf@wipo.int.

The current version of the Disclosure Requirements Table was updated as of December 21, 2023. Further updates will be made available on the WIPO website: www.wipo.int.

Country/ Region	Title	Subject Matter	Trigger of Disclosure	Content of Disclosure	Consequences of non- compliance
Region Andean Community	Decision No. 391 of the Commission of the Andean Community Establishing the Common Regime on Access to Genetic Resources (https://www.wipo.int/wipolex/en/text/223610)	Title 1 Definitions Biological Resources: individuals, organisms or parts of them, populations or any biotic component of value or of real or potential use that contains a genetic resource or its byproducts () Genetic Resources: all biological material that contains genetic information of value or of real or potential use	Disclosure Complementary Provisions () Second. The Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by- products or synthesized products and associated intangible components, that were obtained or developed through an access activity that does not comply with the provisions of this Decision. Furthermore, the Member Country affected may request nullification and bring such actions as are	Disclosure Complementary Provisions () Third. The Competent National Offices on Intellectual Property shall require the applicant to give the registration number of the access contract and supply a copy of it as a prerequisite for granting the respective right, when they are certain or there are reasonable indications that the products or processes whose protection is being requested have been obtained or developed on the basis of genetic resources or their	complianceComplementary Provisions() Second. The Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components, that were obtained or developed through an access activity that does not comply with the provisions of this Decision.Furthermore, the Member Country affected may request nullification and bring such actions as are appropriate in countries that have conferred rights or granted protective title documents

			countries that have conferred rights or granted protective title documents	originated in one of the Member Countries.	
Belgium	Loi du 28 mars 1984 sur les brevets d'invention (Law of March 28, 1984 on Patents) (mise à jour le 22 décembre 2008) (https://wipolex.wipo.int/fr/legislation/details/11665)	Article 15 § 1er [] La matière biologique d'origine végétale ou animale	Article 15 § 1er La demande de brevet doit contenir: [] (6) une mention de l'origine géographique de la matière biologique d'origine végétale ou animale à partir de laquelle l'invention a été développée, lorsque celle-ci est connue.	Article 15 § 1er La demande de brevet doit contenir: [] (6) une mention de l'origine géographique de la matière biologique d'origine végétale ou animale à partir de laquelle l'invention a été développée, lorsque celle-ci est connue.	
Brazil	Law No. 13.123 of May 20, 2015 (Access and Benefits Sharing of Genetic Resources and Associated Traditional Knowledge) (http://www.wipo.int/wipolex/en/details.jsp?id=15741)	Article 47 [] concessão de direito de propriedade intelectual [] sobre produto acabado ou sobre material reprodutivo obtido a partir de acesso a patrimônio genético ou a conhecimento tradicional associado	Article 47 A concessão de direito de propriedade intelectual pelo órgão competente sobre produto acabado ou sobre material reprodutivo obtido a partir de acesso a patrimônio genético ou a conhecimento tradicional associado fica condicionada ao cadastramento ou autorização, nos termos desta Lei.	Article 47 A concessão de direito de propriedade intelectual pelo órgão competente sobre produto acabado ou sobre material reprodutivo obtido a partir de acesso a patrimônio genético ou a conhecimento tradicional associado fica condicionada ao cadastramento ou autorização, nos termos desta Lei.	
	Decreto nº 8.772 de 11 de maio de 2016 que regulamenta a Lei nº 13.123, de 20 de maio de 2015 (<u>https://wipolex.wipo.int/en/legislation/details/16116</u>)				Art. 80. Requerer direito de propriedade intelectual resultante de acesso ao patrimônio genético ou conhecimento tradicional associado,

	no Brasil ou no exterior,
	sem realização de
	cadastro prévio.
	Multa mínima de R\$
	3.000,00 (três mil
	reais) e máxima de R\$
	30.000,00 (trinta mil
	reais), quando se
	tratar de pessoa
	natural.
	Multa mínima de R\$
	10.000,00 (dez mil
	reais) e máxima de R\$
	200.000,00 (duzentos
	mil reais), quando se
	tratar de pessoa
	jurídica enquadrada
	como microempresa,
	empresa de pequeno
	porte ou cooperativas
	de agricultores
	tradicionais com
	receita bruta anual
	igual ou inferior ao
	limite máximo
	estabelecido no
	inciso II do art. 3º da
	Lei Complementar nº
	123, de 2006.
	Multa mínima de R\$
	20.000,00 (vinte mil
	reais) e máxima de R\$
	10.000.000,00 (dez
	milhões de reais),
	para as demais
	pessoas jurídicas

Burundi	Law No. 1/13 of July 28, 2009 relating To Industrial Property in Burundi (https://wipolex.wipo.int/en/legislation/details/8324)	Article 21 genetic or biological resources, traditional knowledge	Article 21 The description must contain a clear indication of the origin of the genetic or biological resources collected in the territory of Burundi and used directly or indirectly in the making of the claimed invention as well as any element of the traditional knowledge which may or may not be linked to these resources that is protected under Title V of this part and that has been used directly or indirectly in the making of the claimed invention without the prior informed consent of its individual or joint creators.	Article 21 The description must contain a clear indication of the origin of the genetic or biological resources collected in the territory of Burundi and used directly or indirectly in the making of the claimed invention as well as any element of the traditional knowledge which may or may not be linked to these resources that is protected under Title V of this part and that has been used directly or indirectly in the making of the claimed invention without the prior informed consent of its individual or joint creators.	Article 406. The competent authority shall be entitled to claim ownership of any patent application filed or any patent granted in a manner which does not comply with the provisions of Article 21 concerning genetic resources.
China	Patent Law of the People's Republic of China (as amended up to October 17, 2020, regarding the Revision of the Patent Law of the People's Republic of China) (https://www.wipo.int/wipolex/en/legislation/details/21027)	Article 26 Genetic resources	Article 26. With regard to an invention-creation accomplished by relying on genetic resources, the applicant shall, in the patent application documents, indicate the direct and original source of the genetic resources.	Article 26. With regard to an invention-creation accomplished by relying on genetic resources, the applicant shall, in the patent application documents, indicate the direct and original source of the genetic resources.	Article 5. No patent right shall be granted for any invention-creation where the acquisition or utilization of the genetic resources, on which the development of the invention-creation relies, violates the provisions of laws or administrative regulations.

				Article 26. If the applicant cannot indicate the original source, he shall state the reasons.
Implementing Rules of the Patent Law of the People's Republic of China (promulgated by Decree No. 306 of the State Council of China on June 15, 2001, and revised by the Decision of January 9, 2010, of the State Council on Amending the Rules for the Implementation of the Patent Law of the People's Republic of China) (https://www.wipo.int/wipolex/en/legislation/details/6504)	Article 26 The genetic resources referred to in the Patent Law means any material taken from human, animal, plant or microorganism, containing genetically functioning units with actual or potential value; the invention-creation accomplished depending on the genetic resources means those invention-creation of which the accomplishment uses the genetic function of genetic resources. Where the applicant seeks to apply for patent for such invention-creation completed on genetic resources, he or it shall so state in the request, fill in prescribed forms issued by the Patent Administration Department under the State Council.	Article 26 The genetic resources referred to in the Patent Law means any material taken from human, animal, plant or microorganism, containing genetically functioning units with actual or potential value; the invention- creation accomplished depending on the genetic resources means those invention-creation of which the accomplishment uses the genetic function of genetic resources. Where the applicant seeks to apply for patent for such invention- creation completed on genetic resources, he or it shall so state in the request, fill in prescribed forms issued by the Patent Administration Department under the State Council.	Article 26 The genetic resources referred to in the Patent Law means any material taken from human, animal, plant or microorganism, containing genetically functioning units with actual or potential value; the invention- creation accomplished depending on the genetic resources means those invention-creation of which the accomplishment uses the genetic function of genetic resources. Where the applicant seeks to apply for patent for such invention-creation completed on genetic resources, he or it shall so state in the request, fill in prescribed forms issued by the Patent Administration Department under the State Council.	Rule 53 In accordance with the provisions of Article 38 of the Patent Law, the circumstances where an application for a patent for invention shall be rejected by the Patent Administration Department under the State Council after examination as to substance are as follows: [] (2) Where the application does not comply with the provisions of [] Article 26, paragraph [] five [] of the Patent Law []

Costa Rica	Law No. 7788 of April 30, 1998, on Biodiversity (as amended up to Law No. 10133 of March 14, 2022) (https://www.wipo.int/wipolex/en/legislation/details/21875)	ARTÍCULO 80. Consulta previa obligada Tanto la Oficina Nacional de Semillas como los Registros de Propiedad Intelectual y de Propiedad Industrial, obligatoriamente deberán consultar a la Oficina Técnica de la Comisión, antes de otorgar protección de propiedad intelectual o industrial a las innovaciones que involucren elementos de la biodiversidad. Siempre aportarán el certificado de origen emitido por la Oficina Técnica de la Comisión y el consentimiento previo.	ARTÍCULO 80. Consulta previa obligada Tanto la Oficina Nacional de Semillas como los Registros de Propiedad Intelectual y de Propiedad Industrial, obligatoriamente deberán consultar a la Oficina Técnica de la Comisión, antes de otorgar protección de propiedad intelectual o industrial a las innovaciones que involucren elementos de la biodiversidad. Siempre aportarán el certificado de origen emitido por la Oficina Técnica de la Comisión y el consentimiento previo. La oposición fundada de la Oficina Técnica impedirá registrar la patente o	ARTÍCULO 80. Consulta previa obligada Tanto la Oficina Nacional de Semillas como los Registros de Propiedad Intelectual y de Propiedad Industrial, obligatoriamente deberán consultar a la Oficina Técnica de la Comisión, antes de otorgar protección de propiedad intelectual o industrial a las innovaciones que involucren elementos de la biodiversidad. Siempre aportarán el certificado de origen emitido por la Oficina Técnica de la Comisión y el consentimiento previo. La oposición fundada de la Oficina Técnica impedirá registrar la patente o protección	ARTÍCULO 80. Consulta previa obligada. Tanto la Oficina Nacional de Semillas como los Registros de Propiedad Intelectual y de Propiedad Industrial, obligatoriamente deberán consultar a la Oficina Técnica de la Comisión, antes de otorgar protección de propiedad intelectual o industrial a las innovaciones que involucren elementos de la biodiversidad. Siempre aportarán el certificado de origen emitido por la Oficina Técnica de la Comisión y el consentimiento previo. La oposición fundada de la Oficina Técnica impedirá registrar la patente o protección de la innovación
			protección de la innovación.	de la innovación.	
Cuba	Decree-Law No. 290 of November 20, 2011, on Inventions and Industrial Designs and Models (<u>http://www.wipo.int/wipolex/en/details.jsp?id=12026</u>)	Articulo 26.1. material biológico	Articulo 26.1 Para obtener una patente, el solicitante presenta ante la Oficina la correspondiente solicitud, que contiene los documentos siguientes:	Articulo 26.1 Para obtener una patente, el solicitante presenta ante la Oficina la correspondiente solicitud, que contiene los documentos siguientes:	Articulo 32.1 En caso de detectarse cualquier omisi6n o irregularidad en la documentaci6n, se expide requerimiento al solicitante para que, previo pago de la tarifa establecida, subsane la misma en un termino

incluido el genetico y sus partes o derivados del que Cuba es país de origen o que está presente en especiesincluido el genetico y sus partes o derivados del que Cuba es país de origen o que está presente en especies2. Si el solicitante no subsana la omision o irregularidad en el termino establecido, se entiende como abandonada la	domesticadas y cultivadas en el país; k) declaración que exprese que el material biológico al que se refiere la invención no ha sido obtenido en el territorio de la Republica de Cuba, en cuyo caso debe indicarse el país de origen y fuente del material biológico y en cuyo caso debe indicarse el país de origen y fuente del material biológico y en cuyo caso combenintos territorio con aquella.			y sus partes derivados de Cuba es país origen o que presente en especies	virizacióny expresa autorización para el acceso a material biológico, expedida por la autoridad competente de conformidad con la legislación vigente en la materia, cuando la invención se refiere a dicho material, incluido el genetico y sus partes o del que s de e estávirial, e resi e estácompetente de conformidad con la legislación vigente en la materia, cuando la invención material, enetico y sus partes o derivados del que cuba es país de origen o que está presente en especies	subsana la omision o irregularidad en el termino establecido, se entiende como abandonada la
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Denmark	Order No. 2111 of November 24, 2021, on Patents and	Part I Chapter 2 3(5)	Part I Chapter 2	Part I Chapter 2	Part I Chapter 2
	Supplementary Protection Certificates	() biological	The contents and	The contents and	The contents and filing
		material	filing of applications	filing of applications	of applications
			[]	[]	[]
	(https://www.wipo.int/wipolex/en/text/584476)		3	3	3
			[]	[]	[]
			(4) If an invention	(4) If an invention	(4) If an invention
			relates to or makes	relates to or makes	relates to or makes use
			use of a biological	use of a biological	of a biological material,
			material, the patent	material, the patent	the patent application
			application shall	application shall	shall contain information
			contain information	contain information	about the geographical
			about the	about the	origin of the material if
			geographical origin	geographical origin	the applicant is aware
			of the material if the	of the material if	thereof.
			applicant is aware	the applicant is	If the applicant is not
			thereof. If the	aware thereof.	aware of the
			applicant is not	If the applicant is	geographical origin of
			aware of the	not aware of the	the material, that shall
			geographical origin	geographical origin	appear from the
			of the material, that	of the material, that	application.
			shall appear from	shall appear from	Lack of information
			the application.	the application.	about the
			Lack of information	Lack of information	geographical origin
			about the	about the	of the material or
			geographical origin	geographical origin	about the applicant's
			of the material or	of the material or	non-awareness
			about the applicant's	about the applicant's	thereof shall not affect the examination
			non-awareness thereof shall not	non-awareness thereof shall not	and other processing
			affect the	affect the	of the patent
			examination and	examination and	application or the
			other processing of	other processing of	validity of the rights
			the patent	the patent	conferred by the
			application or the	application or the	granted patent.
			validity of the rights	validity of the rights	granted pateriti
			conferred by the	conferred by the	
			granted patent.	granted patent.	
			granted patent.	granted patent.	<u> </u>

Djibouti	Law No. 50/AN/09/6th Lof July 19, 2009, on the Protection	Article 34	Article 34	Article 34	Article 41
,	of Industrial Property	genetic or	The description of	The description of	A patent application
		biological	the invention shall	the invention shall	shall be refused if: []
		resources,	disclose the	disclose the	(g) its description or
	(https://wipolex.wipo.int/en/legislation/details/6124)	traditional	invention in a way	invention in a way	claims clearly do not
	,	knowledge	that is sufficiently	that is sufficiently	meet the conditions
			clear and complete	clear and complete	provided for in
			to enable a person	to enable a person	Articles 34 and 35,
			skilled in the art to	skilled in the art to	particularly where
			carry it out. In	carry it out. In	claims are not based
			particular, the	particular, the	on the description;
			description of the	description of the	[]
			invention shall:	invention shall:	
			[]	[]	
			(b) indicate the	(b) indicate the	
			background art	background art	
			which, as far as	which, as far as	
			known to the	known to the	
			applicant, can be	applicant, can be	
			regarded as useful	regarded as useful	
			for understanding the	for understanding	
			invention and the	the invention and the	
			searching and	searching and	
			examination of the	examination of the	
			invention in the event	invention in the	
			of a dispute, and,	event of a dispute,	
			preferably, cite the	and, preferably, cite	
			documents reflecting	the documents	
			such art. If the invention claimed	reflecting such art. If the invention claimed	
			has been	has been developed	
				or obtained directly	
			developed or obtained directly	from genetic or	
			from genetic or	biological resources	
			biological	biological resources	

			resources obtained from a particular source, or from the use of traditional knowledge obtained from a particular community, the description shall indicate the source of these resources or knowledge, as well as the way in which they have been obtained;	obtained from a particular source, or from the use of traditional knowledge obtained from a particular community, the description shall indicate the source of these resources or knowledge, as well as the way in which they have been obtained;	
Ecuador	Reglamento Nacional al Régimen Común de Acceso a los Recursos Genéticos en aplicación a la Decisión N° 391 de la Comunidad Andina (Decreto Ejecutivo Nº 905 de 3 de octubre de 2011) (https://www.wipo.int/wipolex/en/legislation/details/11842)	DISPOSICIONES GENERALES PRIMERA un recurso genético o de un producto derivado del mismo	DISPOSICIONES GENERALES PRIMERA Previo al otorgamiento de un derecho de propiedad intelectual, el Instituto Ecuatoriano de Propiedad Intelectual solicitará la presentación del número del registro del contrato de acceso y copia del mismo, cuando existan indicios razonables o certeza de que los productos o procesos cuya protección se solicita hayan sido obtenidos a partir de un recurso genético o de un producto derivado	DISPOSICIONES GENERALES PRIMERA Previo al otorgamiento de un derecho de propiedad intelectual, el Instituto Ecuatoriano de Propiedad Intelectual solicitará la presentación del número del registro del contrato de acceso y copia del mismo, cuando existan indicios razonables o certeza de que los productos o procesos cuya protección se solicita hayan sido obtenidos a partir de un recurso genético o de un producto derivado del mismo, y que esté en	

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		del mismo, y que	consonancia con lo	
		esté en consonancia	establecido en la	
		con lo establecido en	Constitución y	
		la Constitución y	normativa aplicable.	
		 normativa aplicable.		-
	Organic Code on the Social Economy of Knowledge,	Artículo 282 De la	Artículo 282 De la	Artículo 303 Nulidad
	Creativity and Innovation (of December 9, 2016)	patente y la	patente y la	absoluta de la
		divulgación de	divulgación de	patente La
	(https://wipolex.wipo.int/en/legislation/details/16990)	origen	origen	autoridad nacional
		De acuerdo a lo	De acuerdo a lo	competente en materia
		previsto en los	previsto en los	de derechos
		tratados	tratados	intelectuales, de oficio o
		internacionales de	internacionales de	a solicitud de cualquier
		los cuales el	los cuales el	persona que acredite
		Ecuador es parte,	Ecuador es parte,	legítimo interés, y en
		este Código y su	este Código y su	cualquier momento,
		reglamento	reglamento	declarará la nulidad
		respectivo, en el	respectivo, en el	absoluta de una
		caso de que el	caso de que el	patente, en los
		objeto de una	objeto de una	siguientes casos:
		solicitud de	solicitud de	[]
		patente implique la	patente implique la	7. De ser el caso, si no
		utilización de	utilización de	se hubiese presentado
		recursos genéticos	recursos genéticos	la copia del contrato de
		y los	y los	acceso, cuando los
		conocimientos	conocimientos	productos o
		tradicionales	tradicionales	procedimientos cuya
		asociados , el	asociados, el	patente se solicita han
		solicitante deberá	solicitante deberá	sido obtenidos o
		informar:	informar:	desarrollados a partir de
		1. El país donde se	1. El país donde se	recursos genéticos o de
		obtuvieron esos	obtuvieron esos	sus productos
		recursos o los	recursos o los	derivados de los que el
		conocimientos	conocimientos	Ecuador es país de
		tradicionales	tradicionales	origen;
		asociados; y,	asociados; y,	8. De ser el caso, si no
		2. La fuente, con	2. La fuente, con	se hubiese presentado
		inclusión de	inclusión de	la copia del documento
		pormenores respecto	pormenores	que acredite la licencia
		a la entidad, en su	respecto a la	o autorización de uso
		caso, de la que se	entidad, en su	de los conocimientos
		obtuvieron esos	caso, de la que se	tradicionales de las
			obtuvieron esos	comunidades

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		recursos o los	recursos o los	indígenas,
		conocimientos	conocimientos	afroamericanas o
		tradicionales	tradicionales	locales del Ecuador o
		asociados.	asociados.	los países miembros de
		Deberá igualmente	Deberá igualmente	la Comunidad Andina,
		adjuntar copia de un	adjuntar copia de un	cuando los productos o
		certificado de	certificado de	procesos cuya
		cumplimiento con la	cumplimiento con	protección se solicita
		legislación de	la legislación de	han sido obtenidos o
		acceso a recursos	acceso a recursos	desarrollados a partir de
		genéticos o los	genéticos o los	dichos conocimientos
		conocimientos	conocimientos	de los que el Ecuador o
		tradicionales	tradicionales	cualquiera de
		asociados	asociados	los países miembros de
		reconocido	reconocido	la Comunidad Andina
		internacionalmente.	internacionalmente.	es país de origen;
		Si un certificado de	Si un certificado de	9. Si la patente hubiese
		cumplimiento	cumplimiento	sido concedida en
		reconocido	reconocido	contravención
		internacionalmente	internacionalmente	del artículo 282;
		no es aplicable en el	no es aplicable en el	Cuando las causales
		país proveedor, el	país proveedor, el	indicadas anteriormente
		solicitante deberá	solicitante deberá	sólo afectaren alguna
		proporcionar	proporcionar	de las reivindicaciones
		información	información	o partes de una
		pertinente en cuanto	pertinente en	reivindicación, la
		a la conformidad con	cuanto a la	nulidad se declarará
		el consentimiento	conformidad con el	solamente con respecto
		fundamentado previo	consentimiento	a tales reivindicaciones
		y el acceso y la	fundamentado	o a tales partes de la
		participación justa y	previo	reivindicación, según
		equitativa en los	y el acceso y la	corresponda.
		beneficios, tal como	participación justa	La patente, la
		lo exija la legislación	y equitativa en los	reivindicación o aquella
		nacional del país	beneficios, tal	parte de una
		que aporte los	como lo exija la	reivindicación que fuese
		recursos genéticos	legislación	declarada nula se
		y/o los	nacional del país	reputará nula y sin
		conocimientos	que aporte los	ningún valor desde la
		tradicionales	recursos genéticos	fecha de presentación
		asociados, que sea	y/o los	de la solicitud de la
		el país de origen de	conocimientos	patente.
			CONOCIMENIOS	Datente

			país que haya adquirido los recursos genéticos o los conocimientos tradicionales asociados de conformidad con el Convenio sobre la Diversidad Biológica y los demás tratados internacionales de los que Ecuador es parte.	tradicionales asociados, que sea el país de origen de dichos recursos o un país que haya adquirido los recursos genéticos o los conocimientos tradicionales asociados de conformidad con el Convenio sobre la Diversidad Biológica y los demás tratados internacionales de los que Ecuador es parte.	
Egypt	Law No. 82 of 2002 on the Protection of Intellectual Property Rights (http://www.wipo.int/wipolex/en/details.jsp?id=1301)	Article 13 biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage	Article 13 [] Where the invention involves biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage, the inventor should have acquired the sources in a legitimate manner. []	Article 13 [] Where the invention involves biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage, the inventor should have acquired the sources in a legitimate manner. []	Article 14 The Patent Office may, as stipulated in the Regulations, require the applicant to make any amendments or complements which it shall deem necessary to comply with the provisions of Article 13. If the applicant fails to comply within three months of notification, he shall be considered as having withdrawn his application. The applicant may, within 30 days and in accordance with the conditions stipulated in the Regulations, appeal such request by the Patent Office before the Committee provided for in article 36.

	Council of Ministers Resolution No. 1366 of 2003 issuing Implementing Regulations for Law No. 82 of 2002 on the Protection of Intellectual Property Rights, Books One, Two and Four (http://www.wipo.int/wipolex/en/details.jsp?id=7299)	Article 3 [] plant or animal biological material, traditional medicinal, agricultural, industrial or handicraft knowledge, or cultural or environmental heritage	Article 3 The patent application shall be accompanied by [] 3. Where the application relates to an invention or utility model involving plant or animal biological material, traditional medicinal, agricultural, industrial or handicraft knowledge, or cultural or environmental heritage, it shall be accompanied by documentation proving that the inventor has accessed the source from which the material was obtained in a legitimate manner, according to the legislation applicable in the Arab Republic of Egypt.	Article 3 The patent application shall be accompanied by [] 3. Where the application relates to an invention or utility model involving plant or animal biological material, traditional medicinal, agricultural, industrial or handicraft knowledge, or cultural or environmental heritage, it shall be accompanied by documentation proving that the inventor has accessed the source from which the material was obtained in a legitimate manner, according to the legislation applicable in the Arab Republic of Egypt.	Article 4. Documentation mentioned under items 3, 4, 5, 6 and 7 of Article 3 of these Regulations may be furnished within four months from the filing date of the application. [] If the documents provided for by the first paragraph are not furnished in due time, as the case may be, the application shall be considered as non- existent.
Ethiopia	Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation No. 482/2006 (<u>https://wipolex.wipo.int/en/legislation/details/5559</u>)	Article 17. genetic resources, community knowledge	Article 17. Obligations of Access Permit Holder A person who shall be given an access	Article 17. Obligations of Access Permit Holder A person who shall be given an access	

European	Directive 98/44/EC of the European Parliament and of the	(Paragraph 27 of	permit shall have the following obligations: [] 12/ where he seeks to acquire intellectual property right over the genetic resources accessed or parts thereof, negotiate new agreement with the Institute based on the relevant laws of Ethiopia; 13/ not apply for a patent or any other intellectual property protection over the community knowledge accessed without first obtaining explicit written consent from the Institute; 14/ recognize the locality where the genetic resource or community knowledge accessed from as origin in the application for commercial property protection of the product developed there from; [] Paragraph 27 of the	permit shall have the following obligations: [] 12/ where he seeks to acquire intellectual property right over the genetic resources accessed or parts thereof, negotiate new agreement with the Institute based on the relevant laws of Ethiopia ; 13/ not apply for a patent or any other intellectual property protection over the community knowledge accessed without first obtaining explicit written consent from the Institute; 14/ recognize the locality where the genetic resource or community knowledge accessed from as origin in the application for commercial property protection of the product developed there from; []	Paragraph 27 of the
Union	Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions (http://www.wipo.int/wipolex/en/details.jsp?id=1440)	the Preamble) biological material of plant or animal origin	Preamble. Whereas if an invention is based on biological material of plant or	Preamble. Whereas if an invention is based on biological material of plant or	Preamble. Whereas if an invention is based on biological material of plant or animal origin or

			animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known;	animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known;	if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.
France	Loi n° 2016-1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages (http://www.wipo.int/wipolex/en/details.jsp?id=16565)	Art. L. 412-18II Ressources génétiques et de connaissances traditionnelles associées	Art. L. 412-18II Les utilisateurs de ressources génétiques et de connaissances traditionnelles associées présentent à la ou aux autorités compétentes mentionnées au premier alinéa du présent II les informations prévues à l'article 4 du règlement (UE) n° 511/2014 du 16 avril 2014 précité, dans les cas suivants : [] 2° [] Lorsque [l'utilisation de ressources génétiques et de connaissances traditionnelles associées aux ressources génétiques] conduit à une demande de	Art. L. 412-18II Les utilisateurs de ressources génétiques et de connaissances traditionnelles associées présentent à la ou aux autorités compétentes mentionnées au premier alinéa du présent II les informations prévues à l'article 4 du règlement (UE) n° 511/2014 du 16 avril 2014 []	Article 39 [] Est puni d'un an d'emprisonnement et de 150 000 € d'amende : 1° Le fait d'utiliser des ressources génétiques ou des connaissances traditionnelles associées, au sens de l'article L. 4123 L. 4124, sans disposer des documents mentionnés au 3 de l'article 4 du règlement (UE) n° 511/2014 du Parlement européen et du Conseil, du 16 avril 2014, précité lorsqu'ils sont obligatoires ; 2° Le fait de ne pas rechercher, conserver ou transmettre aux utilisateurs ultérieurs les informations pertinentes sur l'accès et le partage des avantages pour les ressources génétiques et les connaissances traditionnelles

	brevet, les	associées en
	informations	application du même
	mentionnées au	article 4.
	premier alinéa du	L'amende est portée à
	présent II sont	un million d'euros
	adressées à l'Institut	lorsque l'utilisation des
	national de la	ressources génétiques
	propriété industrielle	ou des connaissances
	à la seule initiative	traditionnelles
	du déclarant.	mentionnée au 1° du
	L'Institut national de	présent l a donné lieu à
	la propriété	une utilisation
	industrielle procède	commerciale. II. Les
	aux démarches	personnes physiques
	normales de	ou morales coupables
	l'examen de la	des infractions prévues
	demande de brevet	au I du présent article
	et à l'attribution d'une	encourent également, à
	date de dépôt et	titre de peine
	transmet les	complémentaire,
	informations sans	l'interdiction, pendant
	examen à l'autorité	une durée ne pouvant
	compétente chargée	excéder cinq ans, de
	de l'application des	solliciter, en
	règles édictées par	application des articles
	l'Union européenne	L. 4128 et L. 4129, une
	visant à ce que	autorisation d'accès
	chaque Etat membre	aux ressources
	contrôle que	génétiques ou à
	l'utilisateur sur son	certaines catégories
	territoire de	d'entre elles et aux
	ressources	connaissances
	génétiques et, le cas	traditionnelles
	échéant, de	associées en vue de
	connaissances	leur utilisation
	traditionnelles	commerciale.
	associées à ces	
	ressources y a eu	
	accès dans le	
	respect de toute	
	disposition législative	
	ou réglementaire	
	alors applicable. []	

Germany	Patent Act as published on 16 December 1980 (Federal Law Gazette 1981 I p. 1), as last amended by Article 2 of the Act of 4 April 2016 (https://www.wipo.int/wipolex/en/text/586963)	Section 34a Biological material of plant or animal origin	Section 34a (1) Where an invention is based on biological material of plant or animal origin or if it uses such material, the application should include information on the geographical origin of such material, if known. []	Section 34a (1) Where an invention is based on biological material of plant or animal origin or if it uses such material, the application should include information on the geographical origin of such material, if known. [] (2) If the application includes information on the geographical origin pursuant to the first sentence of subsection (1), the German Patent and Trade Mark Office shall notify this application to the Federal Agency for Nature Conservation (Bundesamt für Naturschutz) as the competent authority within the meaning of section 6 (1) of the Act Implementing the Obligations Under the Nagoya Protocol and Transposing Regulation (EU) No 511/2014 of 25 November 2015 (Federal Law Gazette I p. 2092)	Section 34a (1) [] This shall be without prejudice to the examination of applications or the validity of rights arising from granted patents. []
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				following publication of the information pursuant to section 32 (5).	
India	The Patents Act, 1970 (as amended up to Patents (Amendment) Act, 2005) (https://www.wipo.int/wipolex/en/legislation/details/20694)	Article 10(4)(ii)(D) Biological material	Article 10(4)(ii)(D) (ii) If the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty and by fulfilling the following conditions, namely:— [] (D) disclose the source and geographical origin of the biological material in the specification, when used in an invention.	Article 10(4)(ii)(D) (ii) If the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty and by fulfilling the following conditions, namely:— [] (D) disclose the source and geographical origin of the biological material in the specification, when used in an invention.	Article 25 Opposition to the patent. — (1) Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent on the ground [] (j) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention; (k) that the invention so far as claimed in any claim of the complete specification is anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere (2) At any time after the grant of patent but before the expiry of a period of one year from the date of publication

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		of grant of a patent, any
		person interested may
		give notice of opposition
		to the Controller in the
		prescribed manner on
		any of the following
		grounds, namely: —
		[]
		[]
		Article 64 Revocation
		of patents.
		(1) Subject to the
		provisions contained in
		this Act, a patent,
		whether granted before
		or after the
		commencement of this
		Act, may, be revoked
		on a petition of any
		person interested or of
		the Central Government
		by the Appellate Board
		or on a counter-claim in
		a suit for infringement of
		the patent by the High
		Court on any of the
		following grounds , that
		is to say—
		[]
		(p) that the complete
		specification does not
		disclose or wrongly
		mentions the source
		or geographical origin
		of biological material
		used for the
		invention;
		[]
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Indonesia	Law of the Republic of Indonesia No. 13 of July 28, 2016, on Patents (http://www.wipo.int/wipolex/en/details.jsp?id=16392)	Article 26 Genetic resources and/or traditional knowledge	Article 26 (1) If an invention as being associated with and/or derived from a genetic resource and/ or traditional knowledge, it is mandatory to disclose the origin of the genetic resource and/or traditional knowledge in question in a clear and true manner in its patent description. (2) Information about a genetic resource and/ or traditional knowledge mentioned in sub article (1) is endorsed by a competent authority authorized by the government. (3) Benefit sharing and/or access for the utilization of a genetic resource and/ or traditional knowledge substantiated in sub article (1) is conducted based on national laws and international laws in the realm of genetic resources and traditional	Article 26 (1) If an invention as being associated with and/or derived from a genetic resource and/ or traditional knowledge, it is mandatory to disclose the origin of the genetic resource and/or traditional knowledge in question in a clear and true manner in its patent description. (2) Information about a genetic resource and/ or traditional knowledge mentioned in sub article (1) is endorsed by a competent authority authorized by the government. (3) Benefit sharing and/or traditional knowledge substantiated in sub article (1) is conducted based on national laws and international laws in the realm of genetic	
			the realm of genetic	national laws and	

Italy	Industrial Property Code (Legislative Decree No. 30 of February 10, 2005, as amended up to Law No. 10829 of July 29, 2021) (https://www.wipo.int/wipolex/en/legislation/details/21556)	Article 170 bis. biological material of animal or plant origin	Article 170 bis. Requirements concerning biotechnological inventions [] 2. The provenance of biological material of animal or plant origin, which is the basis of the invention, is to be declared together with the application of the patent both with reference to the country of origin, in order to verify compliance with import and export legislation, and in relation to the biological organism from which it was isolated. [].	Article 170 bis. Requirements concerning biotechnological inventions [] 2. The provenance of biological material of animal or plant origin, which is the basis of the invention, is to be declared together with the application of the patent both with reference to the country of origin, in order to verify compliance with import and export legislation, and in relation to the biological organism from which it was isolated. []	Article 170 bis. Requirements concerning biotechnological inventions [] 7. If the Italian Patent and Trademark Office ascertains the lack of the conditions for patenting a biotechnological invention or the failure to file the declarations under paragraphs 2, 3 and 4, shall proceed in accordance with Article 173, paragraph 7, and in the event it determines the absence of the conditions for patenting as set forth by Articles 81-quater, 81- quinquies and Article 162, it shall reject the application. [Article added by paragraph 1 of Article 87, Legislative Decree No. 131 of 13 August 2010.] Art. 170-ter. Sanctions [] 2. Unless the action constitutes a crime, whoever, in the declaration required by Article 170-bis, paragraph 2, makes false statements concerning the provenance of biological material of animal or
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		plant origin, shall be
		punished with an
		administrative fine
		from 10.000,00 to
		100.000,00 Euros.
		[]
		4. Within the minimum
		and maximum limits
		established by this
		article, the amount of
		the administrative fines
		shall be determined
		taking account the
		criteria set forth by
		Article 11 of Law No.
		689 of 24 November
		1981, the different
		potential for causing
		harm to the protected
		interest that each
		violation has in the
		abstract, the specific
		personal qualities and
		the property advantage
		that the violation can
		bring to the guilty party
		or the person or entity in
		whose interest he acts.
		[]
		r)
		Article 173.
		Observations
		7. Before rejecting in full
		or in part an application
		or a related request, for
		reasons that were not
		set forth in observations
		pursuant to paragraph
		1, the Italian Patent and
		Trademark Office
		assigns the applicant a term of two months to
		submit observations.

					Once that term has expired, if no observations have been submitted or if the Office does not believe that it can accept those submitted, the application or request is rejected in full or in part .
Iran	Regulations of the Law on Preservation and Utilization of Genetic Resources (2021) (as amended in 2023) (<u>http://nazarat.shora-</u> <u>rc.ir/Forms/FileLoad.aspx?id=qLFdp8+nQ+w=&TN=I7tLyhy</u> <u>Oobj0SooAFUE3m3zd2MHOJ7gNcJaMEmtrHM4=&NF=bH</u> <u>iIRfspeW0=</u>)	Article 4: The following matters shall not be regarded as invention which is the subject of this law or shall be out of the scope of patent protection: 5- Plants, animals, microorganisms and their components as they are found in nature, plant and animal varieties and their genetic components, natural biological derivatives and also procedures which are basically biological and natural. Notice 1: Genetically manipulated microorganisms and microbiological procedures of their production and duplication which are achieved through direct human interference in	Article 15: The following documents shall be annexed to the application: Notice: With regard to biological resources which belong to other countries, subject to reciprocity, permit of access shall be required from the applicant.	Article 16: Where the invention is related to biotechnology and genetic resources, an applicant is required to file the following information and documents as annexes to his/her application: 1-Declaration of the geographical origin of the natural biological resource used for carrying out the invention and the manner of access to the resources, 2- Declaration of the place of preservation and the manner of access with regard to the biological resources whose geographical origin is unknown,	Article 67: The competent court shall invalidate a patent where: Notice 1: With regard to the genetic and biological resources and components which are patentable according to this Act, furnishing of false information as to the geographical origin, the place of preservation or the manner of access to the applied genetic resource and also non-compliance with the laws and regulations related to the manner of access to genetic resources shall result in invalidation of patent. Article 8: The following acts shall constitute offence and the perpetrator shall be condemned to the following

	genetic composition and have characteristics which cannot be achieved from natural species normally and also biological procedures based on technical design and interference and possessing patenting conditions, shall not be regarded as matters cited in this paragraph.		3- Certification of deposit of genetic or biological samples with preservation centers for genetic and biological storages, when, upon discretion of the patent office, their description is impossible.	punishments relevantly by the sentence of the competent court: a) Access to and utilization of genetic resources without compliance with the provisions of this law and exportation of genetic resources for the purpose of access to and utilization of genetic resources without authorization of the related responsible institution shall, respectively, result in condemnation to one or several types of level 5 and 6 of Discretionary Punishments. ()
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Kyrgyzstan	Law of the Kyrgyz Republic No. 116 of July 31, 2007, on the Protection of Traditional Knowledge (<u>http://www.wipo.int/wipolex/en/details.jsp?id=5571</u>)	Traditional knowledge	Article 8. Patenting of subject-matters created on the base of Traditional Knowledge	Article 8. Patenting of subject-matters created on the base of Traditional Knowledge
			[] When patenting the subject-matters created on the base of Traditional Knowledge, materials of the application must contain reveal of origin of Traditional Knowledge which is used as prior art or prototype. The applicant shall indicate the source of making Traditional Knowledge available to the public. []	[] When patenting the subject-matters created on the base of Traditional Knowledge, materials of the application must contain reveal of origin of Traditional Knowledge which is used as prior art or prototype. The applicant shall indicate the source of making Traditional Knowledge available to the public. []
				Article 9. Application for registration and granting the right to use Traditional Knowledge or for granting the right

to use registered Traditional Knowledge [] An application shall contain the following: 1) application for traditional knowledge
registration and granting the right to use Traditional Knowledge or granting the right to use registered Traditional Knowledge stating the applicant as well as his location and place of residence;
2) specific and complete description of Traditional Knowledge, including: point of origin of Traditional Knowledge (borders of a geographic object); description of genetic resource,
genetic resource, which is being used in connection with particular traditional knowledge; field of application and expected positive result of traditional

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	knowledge used;	
	information	
	relevant to	
	previously issued	
	publications	
	regarding a	
	particular	
	traditional	
	knowledge.	
	The following	
	documents shall be	
	attached to the	
	application:	
	1) An official	
	document granted by	
	the competent	
	authority confirming	
	a practical	
	applicability of	
	Traditional	
	Knowledge and	
	positive result of use	
	thereof in	
	appropriate field of	
	activity.	
	2) Conclusion of the	
	competent body	
	(bodies) confirming	
	membership of the	
	applicant in a local	
	community and/or is	
	located in	
	geographic object for	
	which Traditional	
	Knowledge is	
	pertained to.	
	In case of filing the	
	application for	
	registration of	
	Traditional	
	Knowledge by State	
	bodies, the said	
	Knowledge by State bodies, the said	

				conclusion shall not be required. 3) For foreign applicant a document confirming his/her right for the claimed Traditional Knowledge in the country of origin. []	
Namibia	Industrial Property Act, 2012 (Act No. 1 of 2012) (Amended by Act No. 8 of 2016) (https://www.wipo.int/wipolex/en/legislation/details/21942)	Application for a patent Section 24 (2) biological resources or associated indigenous or traditional knowledge	Application for a patent Section 24 (2) Where the subject matter of a patent application is derived from or developed with biological resources or associated indigenous or traditional knowledge, the application for a patent the country providing the resources or associated indigenous or traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin and any other	Application for a patent Section 24 (2) Where the subject matter of a patent application is derived from or developed with biological resources or associated indigenous or traditional knowledge, the applicant must disclose in the application for a patent the country providing the resources or associated indigenous or traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin and any other information	Invalidation of patent Section 65 [] (3) Subject to section 67, the Tribunal must invalidate the patent if the person requesting the invalidation proves that any one of the following grounds for invalidation applies to the patent, namely – [] (e) that any of the requirements of sections [] 24 [] has not been complied with.

			information regarding the source or nature of the resources as may be prescribed.	regarding the source or nature of the resources as may be prescribed.	
Norway	Patents Act (Act No. 9 of December 15, 1967) (consolidated version of 2019)	Chapter 2	Chapter 2	Chapter 2	Chapter 2
	(https://www.wipo.int/wipolex/en/legislation/details/19563)	Section 8b.	Section 8b. If an invention	Section 8b. If an invention	Section 8b. []
	(Official English version available at https://www.patentstyret.no/en/norwegian-patents-act)	Biological material and traditional knowledge	concerns or uses biological material or traditional knowledge, the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). If it follows from the national law in the providing country that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained.	concerns or uses biological material or traditional knowledge, the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). If it follows from the national law in the providing country that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained.	Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code § 221. The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.
			If the providing country is not the same as the	If the providing country is not the	
			country of origin of the biological material or the traditional	same as the country of origin of the biological material or the traditional	
			knowledge, the	knowledge, the	

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application shall also application shall also	
state the country of state the country of	
origin. origin .	
[] []	
If the national law If the national law in	
in the country of the country of origin	
origin requires that requires that access	
access to to biological material	
biological material or use of traditional	
or use of traditional knowledge shall be	
knowledge shall be subject to prior	
subject to prior consent, the	
consent, the application shall	
application shall state whether such	
state whether such consent has been	
consent has been obtained . If the	
obtained. If the information set out in	
information set out this subsection is not	
in this subsection known, the	
is not known, the applicant shall	
applicant shall state state that.	
that.	
The duty to disclose	
[] information	
concerning biological	
When the biological material under the	
material is acquired first and second	
in accordance with paragraphs applies	
Art. 12 No. 2 and 3 even where the	
of the International inventor has altered	
Treaty on Plant the structure of the	
Genetic Resources received material.	
for Food and The duty to disclose	
Agriculture of information does not	
November, 3, 2001 , apply to biological	
a copy of a standard material derived from	
material transfer the human body.	
agreement according When the biological	
to Art 12.4 of the material is acquired	
Treaty shall in accordance with	
accompany the Art. 12 No. 2 and 3	
patent application of the International	
instead of the Treaty on Plant	

			information mentioned in paragraphs two and three. []	Genetic Resources for Food and Agriculture of November, 3, 2001, a copy of a standard material transfer agreement according to Art 12.4 of the Treaty shall accompany the patent application instead of the information mentioned in paragraphs two and three. []	
	Patent Regulations (Regulations No. 1417 of December 14, 2007, to the Norwegian Patents Act) (consolidated version of 2017, status as at September 1, 2017) (https://wipolex.wipo.int/en/legislation/details/18482)	Contents of the patent applications	Chapter 1. National Patent Applications Section 2. Contents of the Application The application shall contain the following: [] 8. information about the providing country and the country of origin for biological material in accordance with section 8b of the Patents Act []	Chapter 1. National Patent Applications Section 2. Contents of the Application The application shall contain the following: [] 8. information about the providing country and the country of origin for biological material in accordance with section 8b of the Patents Act []	
Panama	Executive Decree No. 257 of October 17, 2006 regulating Article 71 of the General Law on Environment (Law No. 41 of July 1, 1998) (http://www.wipo.int/wipolex/en/text.jsp?file_id=189178)	Articulo 23 [] (f) material genético. recurso genético y/o biológico	Articulo 23: Todos los Contratos de Acceso serán válidos por el periodo que determine la UNARGEN en consulta con el CCT e incluirán las	Articulo 23: Todos los Contratos de Acceso serán válidos por el periodo que determine la UNARGEN en consulta con el CCT e incluirán las	Artículo 52: El incumplimiento de las disposiciones establecidas en el presente Decreto Ejecutivo será sancionado con:

siguientes obligaciones con el Estado: [] f) Toda solicitud de patente de invención o procedimiento que sea elevada a la Dirección General de Propiedad Industrial del Ministerio de Comercio e Industrias y/o cualquier oficina de patentes de los países miembros de la Organización Mundial de la Propiedad Intelectual (OMPI) deberá comunicar	siguientes obligaciones con el Estado: [] f) Toda solicitud de patente de invención o procedimiento que sea elevada a la Dirección General de Propiedad Industrial del Ministerio de Comercio e Industrias y/o cualquier oficina de patentes de los países miembros de la Organización Mundial de la Propiedad Intelectual (OMPI) deberá comunicar por escrito el origen y procedencia del	 a) Amonestación escrita; b) Multa impuesta por la ANAM de acuerdo a lo previsto en el artículo 114 de la Ley 41 de 1998. Cuando se trata de persona jurídica, la multa se fijará de conformidad al tipo de actividad y beneficios que se obtengan de los productos obtenidos; c) Cierre temporal o definitivo del establecimiento o laboratorio; d) Inhabilitación para contratar con el Estado para lograr acceso a los recursos genéticos y biúq uímiws;
patentes de los	la Organización	laboratorio;
países miembros	Mundial de la	d) Inhabilitación para
Mundial de la	(OMPI)	Estado para lograr
Propiedad	deberá comunicar	acceso a los recursos
deberá comunicar	y procedencia del	biúq uímiws;
por escrito el origen	material genético.	e) Cancelación
y procedencia del	recurso genético	temporal o definitiva
material genético.	y/o	del permiso de
recurso genético y/o	biológico utilizado	acceso.
biológico utilizado en el desarrollo de la invención o el	en el desarrollo de la invención o el procedimiento, a	
procedimiento, a titulo de información; []	titulo de información; []	

Peru	Law No. 27811 of 24 July 2002, introducing a Protection	Collective	COMPLEMENTARY	COMPLEMENTARY	COMPLEMENTARY
	Regime for the Collective Knowledge of Indigenous	knowledge	PROVISIONS	PROVISIONS	PROVISIONS
	Peoples derived from Biological Resources	C	SECOND	SECOND	SECOND. Submission
		Article 2(b)	Submission of the	Submission of the	of the license contract
	(http://www.wipo.int/wipolex/en/details.jsp?id=3420)	"Collective	license contract as a	license contract as a	as a requirement for
	,	knowledge" means	requirement for	requirement for	obtaining a patent.
		the accumulated,	obtaining a	obtaining a	Where a patent is
		transgenerational	patent. Where a	patent. Where a	applied for in respect of
		knowledge evolved	patent is applied	patent is applied for	goods or processes
		by indigenous	for in respect of	in respect of goods	produced or developed
		peoples and	goods or	or processes	on the basis of
		communities	processes	produced or	collective knowledge,
		concerning the	produced or	developed on the	the applicant shall be
		properties, uses and	developed on the	basis of collective	obliged to submit a copy
		characteristics of	basis of collective	knowledge, the	of the license contract
		biological diversity.	knowledge, the	applicant shall be	as a prior requirement
		The intangible	applicant shall be	obliged to submit a	for the grant of the
		components referred	obliged to submit a	copy of the license	rights concerned,
		to in Decision 391 of	copy of the license	contract as a prior	except where the
		the Commission of	contract as a prior	requirement for the	collective
		the Cartagena	requirement for the	grant of the rights	knowledge
		Agreement include	grant of the rights	concerned, except	concerned is in
		this type of collective	concerned, except	where the collective	the public
		knowledge.	where the collective	knowledge	domain. Failure
			knowledge	concerned is in the	to comply with
			concerned is in the	public domain.	this obligation
		PROVISIONS SECOND.	public domain.	Failure to comply	shall be a cause
		Submission of the	Failure to comply with this obligation	with this obligation shall be a cause of	of refusal or
		license contract as a	shall be a cause of	refusal or	invalidation, as the case may
		requirement for	refusal or	invalidation, as the	be, of the
		obtaining a patent.	invalidation, as the	case may be, of the	patent
		Where a patent is	case may be, of the	patent concerned.	concerned.
		applied for in respect	patent concerned.		concerned.
		of goods or			
		processes produced			
		or developed on the			
		basis of collective			
		knowledge, the			
		applicant shall be			
		obliged to submit a			
		copy of the license			
		contract as a prior			
		requirement for the			
		grant of the rights			

		concerned, except where the collective knowledge concerned is in the public domain. Failure to comply with this obligation shall be a cause of refusal or invalidation, as the case may be, of the patent concerned.			
Philippines	Philippine Technology Transfer Act of 2009 (Republic Act No. 10055) https://wipolex.wipo.int/en/legislation/details/9605		Article III, Sec. 8(c) The following are the rights and responsibilities of the [research and development institutes and/or institutions] RDIs that availed of research funds from [Government Funding Agencies] GFAs: [] (c) Notify the GFA within a reasonable time of all IPR applications, licenses and assignments made. All applications for IP protection shall	Article III, Sec. 8(c) The following are the rights and responsibilities of the [research and development institutes and/or institutions] RDIs that availed of research funds from [Government Funding Agencies] GFAs: [] (c) Notify the GFA within a reasonable time of all IPR applications, licenses and assignments made. All applications for IP protection shall	

	disclose any biodiversity and genetic resource, traditional knowledge, and indigenous knowledge, systems and practices as these terms are defined in Republic Act No. 8371 or the Indigenous Peoples Rights Act and Republic Act No. 9.147 or The Wildlife Act []	systems and practices as these terms are defined in Republic Act No. 8371 or the Indigenous Peoples Rights Act and		
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Implementing Rules and Regulations of Republic Act No.	Rule 12	Rule 12	Rule 12	Rule 12
--	------------------------	-----------------------	-----------------------	----------------------------
10055 (Joint Administrative Order No. 02-2010)	[]	[]	[]	[]
	Section 3	Section 3.	Section 3.	Section 3.
(http://www.wipo.int/wipolex/en/details.jsp?id=9629)	[]	Disclosures.	Disclosures.	Disclosures.
	(c) [] biodiversity,	Disclosure of	Disclosure of	iii. Where the RDI, for
	genetic resources or	potential IPRs	potential IPRs	reasons beyond its
	materials associated	and/or all	and/or all	control, does not have
	traditional knowledge,	biodiversity and	biodiversity and	the necessary
	and indigenous	genetic resource,	genetic resource,	information to fulfill the
	knowledge, systems	traditional	traditional	disclosure requirement
	and practices.	knowledge, and	knowledge, and	pertaining to any
	and practices.	indigenous	indigenous	biodiversity, genetic
				resources or materials,
		knowledge, systems	knowledge, systems	
		and practices shall	and practices shall	traditional knowledge,
		be governed by the	be governed by the	and indigenous
		following rules:	following rules:	knowledge, systems
		[]	[]	and practices, such as,
		(c) With respect to	(c) With respect to	for instance, where a
		biodiversity, genetic	biodiversity, genetic	plant stored in a gene
		resources or	resources or	bank was collected
		materials associated	materials associated	decades ago and no
		Traditional	Traditional	information about its
		knowledge, and	knowledge, and	source exists, the RDI
		indigenous	indigenous	shall submit an affidavit
		knowledge, systems	knowledge, systems	from its researcher/s
		and practices,	and practices,	that the latter do not
		the following	the following	have the necessary
		provisions shall	provisions shall	information or that the
		govern:	govern:	source is unknown, and
		i. The [Research and	i. The [Research and	state the reasons
		Development	Development	thereof. The GFA shall
		Institutes] RDI shall	Institutes] RDI shall	review the affidavit to
		provide the	provide the	determine if this will
		[Government	[Government	constitute compliance
		Funding Agencies]	Funding Agencies]	with the disclosure
		GFA with a written	GFA with a written	requirement under
		disclosure on the	disclosure on the	this rule.
		following: (1) any	following: (1) any	[]
		biodiversity, genetic	biodiversity,	v. A national or
		resources or	genetic resources	international IPR
		materials, associated	or materials,	application filed by the
		traditional	associated	RDI before the
		knowledge, and	traditional	appropriate IP office
		indigenous	knowledge, and	shall include in the
		knowledge,	indigenous	abstract and/or

systems and	knowledge,	description of said
practices utilized in	systems and	application the same
or which formed as	practices utilized in	disclosure on
basis in the	or which formed as	biodiversity, genetic
development of the	basis in the	resources or materials,
subject matter	development of the	associated traditional
contained in the IPR	subject matter	knowledge, and
application; (2) the	contained in the	indigenous knowledge,
primary source of	IPR	systems and practices
any biodiversity,	application; (2) the	utilized in or which
genetic resources or	primary source of	formed as basis in the
materials, associated	any biodiversity,	development of the
traditional	genetic resources	subject matter
knowledge, and	or materials,	contained in the said
indigenous	associated	application,
knowledge, systems	traditional	notwithstanding that
and practices utilized	knowledge, and	such disclosure may
in or which	indigenous	not be required for the
formed as basis in	knowledge,	grant or issuance of
the subject matter	systems and	certificate of IPR
contained in the IPR	practices utilized in	registration.
application; or (3) the	or which	-
secondary source, if	formed as basis in	
no information about	the subject matter	
the primary source is	contained in the	
available.	IPR	
ii. The disclosure	application; or (3)	
requirement under	the secondary	
this section shall	source, if no	
apply when the	information about the	
subject matter	primary source is	
contained in a	available.	
national or	[]	
international IPR	iii. Where the RDI,	
application is	for reasons beyond	
directly based on	its control, does not	
any biodiversity,	have the necessary	
genetic resources	information to fulfill	
or materials,	the disclosure	
traditional	requirement	
knowledge, and	pertaining to any	
indigenous	biodiversity, genetic	
knowledge,	resources or	
systems and	materials, traditional	
	matchais, traditional	

the RDI has had indigenous	
access to prior to knowledge, systems	
the filing of the IPR and practices, such	
application. The as, for instance,	
subject matter where a plant stored	
contained in the IPR in a gene bank was	
application must collected decades	
depend on the ago and no	
specific properties of, information about its	
or must be source exists, the	
consciously derived RDI shall submit an	
from, such affidavit from its	
biodiversity and researcher/s that	
genetic resource or the latter do not	
materials, traditional have the necessary	
knowledge, and information	
indigenous or that the source	
knowledge, systems is unknown, and	
and practices. state the reasons	
iii. Where the RDI, thereof. The GFA	
for reasons beyond shall review the	
its control, does affidavit to determine	
not have the if this will constitute	
necessary compliance with the	
information to fulfill disclosure	
the disclosure requirement under	
requirement this rule.	
pertaining to any []	
biodiversity, v. A national or	
genetic resources international IPR	
or materials, application filed by	
traditional the RDI before the	
knowledge, and appropriate IP office	
indigenous shall include in the	ļ
knowledge, abstract and/or	
systems and description of said	
practices, such as, application the same	
for instance, where a disclosure on	
plant stored in a biodiversity ,	
gene bank was genetic resources	
collected decades or materials ,	
ago and no associated	
information about its traditional	
source exists, the knowledge, and	ļ
RDI shall submit an indigenous	

affidavit from its knowledge,
researcher/s that the systems and
latter do not have the practices utilized in
necessary or which formed as
information basis in the
or that the source is development of the
unknown, and state subject matter
the reasons thereof. contained in the
The GFA shall said application,
review the affidavit to notwithstanding that
determine if this will such disclosure may
constitute not be required for
compliance with the the grant or issuance
disclosure of certificate of IPR
requirement under registration.
this rule.
[]
v. A national or
international IPR
application filed by
the RDI before
the appropriate IP
office shall include
in the abstract and/or
description of said
application the same
disclosure on
biodiversity, genetic
resources or
materials, associated
traditional
knowledge, and
indigenous
knowledge, systems
and practices
utilized in or which
formed as basis in
the development of
the subject matter
contained in the
said application,
notwithstanding that
such disclosure may

Rules and Regulations on Intellectual Property Rights Application and Registration Protecting the Indigenous Knowledge Systems and Practices of the Indigenous Peoples and Indigenous Cultural Communities (approved by Joint IPOPHL-NCIP Administrative Order No. 01, 2016) https://wipolex.wipo.int/en/legislation/details/19227	RULE 2 Scope These Rules and Regulations apply to the examination and registration of intellectual property rights applications in	not be required for the grant or issuance of certificate of IPR registration. RULE 2 Scope These Rules and Regulations apply to the examination and registration of intellectual property rights	RULE 6 Disclosures on intellectual property rights applications a) An intellectual property right application filed in the IDORHU shall	RULE 6 Disclosures on intellectual property rights applications d) The registration for an intellectual property right that uses IKSP in the subject matter of the application chall entry
	the IPOPHL that use the IKSP of the indigenous and cultural communities and encourage tradition- based creations and innovations. RULE 4 Definition of terms "Indigenous Knowledge Systems and Practices" and "IKSP" refer to systems, institutions, mechanisms and technologies	applications in the IPOPHL that use the IKSP of the indigenous and cultural communities and encourage tradition-based creations and innovations.	the IPOPHL shall disclose any IKSP that is used in the subject matter of the application including the source or geographical origin of the IKSP used in the application. The intellectual property right application shall contain the disclosure of IKSP including a statement of compliance to the requirement of free and prior informed	application shall only be effected upon compliance with the disclosure requirement under these Rules and Regulations, particularly, the required free and prior informed consent of the indigenous cultural communities, notwithstanding that such disclosure is not required for the grant of certificate of intellectual property right registration. In case a registration has been
	comprising a unique body of knowledge evolved through time that embody patterns of relationships between and among peoples and between peoples, their lands and resource		consent of the indigenous cultural communities concerned.	issued in violation of these Rules and Regulations, the IPOPHL may, in accordance with its rules and regulations, cancel the registration.

environment,
including such
spheres of
relationships which
may include social,
political, cultural,
economic, religious
spheres, and which
are the direct
outcome of the
indigenous peoples'
responses to certain
needs consisting of
adaptive
mechanisms which
have allowed
indigenous peoples
to survive and thrive
within their given
socio-cultural and
biophysical
conditions (<i>Rule II</i>
Section 1(f) NCIP
Administrative Order
No. 01-98).
The reference to
IKSP also means
traditional cultural
expressions or
traditional
knowledge and
covers distinctive
signs and symbols
associated with the
indigenous peoples
and indigenous
cultural communities
and shall not be
limited to a specific
technical field, and
may include
agricultural,

		environmental and			
		medical knowledge			
		and knowledge			
		associated with			
		genetic resources.			
Romania	Implementing Regulations of the Patent Law No. 64/1991	ARTICLE 16	ARTICLE 16	ARTICLE 16	
Nomania	(approved by Government Decision No. 547/2008)	ARTICLE IO	ANTICLE IO	ARTICLE IO	
	(approved by Government Decision No. 347/2000)	Description of the	Description of the	Description of the	
	(http://www.wipo.int/wipolex/en/details.jsp?id=8457)	invention	invention	invention	
		invention			
		Traditional	(1) The description of	(1) The description of	
		knowledge	the invention	the invention	
			according to Art. 14	according to Art. 14	
			paragraph (1) letter	paragraph (1) letter	
			c) of the	c) of the	
			Law shall contain the	Law shall contain the	
			following:	following:	
			[]	[]	
			c) presentation of the	c) presentation of the	
			prior art considered	prior art considered	
			by the applicant to	by the applicant to	
			be useful for	be useful for	
			understanding,	understanding,	
			performing the	performing the	
			documentary search	documentary search	
			and examining the	and examining the	
			claimed invention,	claimed invention,	
			with the indication of	with the indication of	
			the documents which	the documents which	
			substantiate it; at	substantiate it; at	
			least one solution	least one solution	
			considered to be the	considered to be the	
			closest to the	closest to the	
			claimed invention	claimed invention	
			shall be presented;	shall be presented;	
			where the prior art also contains	where the prior art also contains	
			traditional	traditional	
			knowledge , this and	knowledge, this and	
			its source, if known,	its source, if	
			shall explicitly be	known, shall	
			indicated in the	explicitly be	
				evhicitità ne	
			description;		

			[]	indicated in the description; []	
	Law No. 64/1991 on Patents (as amended up to Law No. 83/2014) (https://wipolex.wipo.int/en/legislation/details/15734)				Art. 53 – (1) Failure to meet one or more of the formal requirements concerning the patent application shall only constitute grounds for revocation or cancellation of the patent, either wholly or in part, where said failure resulted from fraudulent intentions. (2) A patent shall not be revoked or cancelled, either wholly or in part, without giving the owner the possibility to present observations concerning the revocation or cancellation and to make, in a reasonable period of time, amendments or corrections allowed by the Law and the corresponding implementing regulations.
Samoa	Intellectual Property Act 2011 (as amended up to Property Amendment Act 2018, Act No. 16 of 2018) (<u>http://www.wipo.int/wipolex/en/details.jsp?id=13492</u>)	Article 7 biological material or knowledge available within any local or indigenous community	Article 7- Application for a patent [] (3) An application must contain the following: [] (g) a statement stating whether or not the invention for	Article 7- Application for a patent [] (3) An application must contain the following: [] (g) a statement stating whether or not the invention	Article 7- Application for a patent [] (12) If an applicant fails to provide evidence as directed by the Registrar under subsection (10), the Registrar may, cease to deal further with the application.

	which protection is claimed is based on knowledge available within any local or indigenous community whether from Samoa or elsewhere; (h) a statement disclosing the source and geographical origin of any biological material used for the invention; [] (10) Subject to subsection (11), if the application is based on or derived from biological material or knowledge available within any local or indigenous community the Registrar may direct the applicant to furnish evidence as to the applicant's title or authority to make use of such material or knowledge. []22. Application for an innovation patent [] (3) An application must contain: []	for which protection is claimed is based on knowledge available within any local or indigenous community whether from Samoa or elsewhere; (h) a statement disclosing the source and geographical origin of any biological material used for the invention; [] (10) Subject to subsection (11), if the application is based on or derived from biological material or knowledge available within any local or indigenous community the Registrar may direct the applicant to furnish evidence as to the applicant's title or authority to make use of such material or knowledge. [] 22. Application for an innovation patent [] (3) An application	 17. Invalidation- (1) Any interested person may apply to the Supreme Court to invalidate a patent. (2) The Supreme Court must invalidate the patent if the applicant proves that: (a) any of the requirements of sections 5 and sections 7 to 10 are not fulfilled; [] 22. Application for an innovation patent [] (12) When an applicant fails to provide evidence as directed by the Registrar under subsection (10), the Registrar may cease to deal further with the application. 28. Invalidation-(1) Any interested person may apply to the Registrar to invalidate an innovation patent. (2) The Registrar must invalidate the innovation patent if the applicant proves that: [] (b) the description and the claims do not apply with the
	[]	(3) An application must contain:	comply with the

South	Patents Amendment Act 2005 (Act No. 20 of 2005)	(Section 2)	(g) a statement stating whether or not the invention for which protection is claimed is based on knowledge available within any local or indigenous community whether from Samoa or elsewhere; and (h) a statement disclosing the source and geographical origin of any biological material used for the invention; [] (10) Subject to subsection (11), if the application is based on or derived from biological material or knowledge available within any local or indigenous community the Registrar may direct the applicant to furnish evidence as to the applicant's title or authority to make use of such material or knowledge.	[] (g) a statement stating whether or not the invention for which protection is claimed is based on knowledge available within any local or indigenous community whether from Samoa or elsewhere; and (h) a statement disclosing the source and geographical origin of any biological material used for the invention; [] (10) Subject to subsection (11), if the application is based on or derived from biological material or knowledge available within any local or indigenous community the Registrar may direct the applicant to furnish evidence as to the applicant's title or authority to make use of such material or knowledge. Amendment of	requirements of section 20 and sections 22, to 25; []
Africa	(http://www.wipo.int/wipolex/en/details.jsp?id=5765)	genetic resource	section 30 of Act 57 of 1978, as amended	section 30 of Act 57 of 1978, as amended	(1) Any person may at any time apply in the

	ndigenous biological	by section 33 of Act	by section 33 of Act	prescribed manner for
	esource	38 of 1997	38 of 1997	the revocation of a
	raditional	2. Section 30 of the	2. Section 30 of the	patent on any of the
kn	nowledge	principal Act is	principal Act is	following grounds only,
		hereby amended by	hereby amended by	namely
Ge	Genetic resource	the insertion after	the insertion after	[]
m	neans	subsection 25	subsection 25	(g) that the prescribed
(a	a) any indigenous	(3) of the following	(3) of the following	declaration lodged in
ge	enetic material; or	subsections:	subsections:	respect of the
	b) the genetic			application for the
	otential or	"(3A) Every applicant	"(3A) Every applicant	patent or the statement
ch	haracteristics of	who lodges an	who lodges an	lodged in terms of
ar	ny indigenous	application for a	application for a	section 30(3A) contains
sp	pecies.	patent accompanied	patent accompanied	a false statement or
		by a complete	by a complete	representation which is
Ind	ndigenous biological	specification shall,	specification shall,	material and which the
	esource means an	before acceptance	before acceptance of	patentee knew or ought
	ndigenous biological	of the application,	the application,	reasonably to have
re	esource as defined	lodge with the	lodge with the	known to be false at the
in	n section 1 of the	registrar a statement	registrar a	time when the
Na	lational	in the prescribed	statement in the	declaration statement or
Er	Invironmental	manner stating	prescribed manner	representation was
Ma	lanagement:	whether or not the	stating whether or	made.
Bi	Biodiversity Act,	invention for which	not the invention	
20	004 (Act No. 10 of	protection is claimed	for which	
		is based on or	protection is	
	,	derived from an	claimed is based	
Tr	raditional	indigenous biological	on or derived from	
kn	nowledge means	resource, genetic	an indigenous	
	he knowledge that	resource, or	biological resource,	
	in indigenous	traditional knowledge	genetic resource,	
	community has	or use.	or	
	egarding the use of	(3B) The registrar	traditional	
	in indigenous	shall call upon the	knowledge or use.	
	iological resource	applicant to furnish	(3B) The registrar	
	or a genetic	proof in the	shall call upon the	
	esource.	prescribed manner	applicant to furnish	
		as to his or her title	proof in the	
		or authority to make	prescribed manner	
		use of the	as to his or her title	
		indigenous biological	or authority to	
		resource, genetic	make use of the	
		resource, or of the	indigenous	
			inalgenous	

			traditional knowledge or use if an applicant lodges a statement that acknowledges that the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use.".	biological resource, genetic resource, or of the traditional knowledge or use if an applicant lodges a statement that acknowledges that the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use.".	
Spain	Ley N° 24/2015, de 24 de julio de 2015, de Patentes (modificada por la Ley N° 6/2018, de 3 de julio de 2018) (https://wipolex.wipo.int/en/legislation/details/16711)	Artículo 23(2) materia biológica	Artículo 23. Requisitos de la solicitud. [] 2. Cuando la invención se refiera a materia biológica de origen vegetal o animal la solicitud deberá incluir la mención de su origen geográfico o la fuente de procedencia de dicha materia si estos datos fueran conocidos. Esta información no prejuzgará la validez de la patente. []	Artículo 23. Requisitos de la solicitud. [] 2. Cuando la invención se refiera a materia biológica de origen vegetal o animal la solicitud deberá incluir la mención de su origen geográfico o la fuente de procedencia de dicha materia si estos datos fueran conocidos. Esta información no prejuzgará la validez de la patente. En los supuestos previstos en el Reglamento (UE) n.º 511/2014 del Parlamento Europeo	Artículo 23. Requisitos de la solicitud. [] 2. Cuando la invención se refiera a materia biológica de origen vegetal o animal la solicitud deberá incluir la mención de su origen geográfico o la fuente de procedencia de dicha materia si estos datos fueran conocidos. Esta información no prejuzgará la validez de la patente. En los supuestos previstos en el Reglamento (UE) n.º 511/2014 del Parlamento Europeo y del Consejo, de 16 de abril de 2014, relativo a las medidas de cumplimiento de los usuarios del Protocolo

				y del Consejo, de 16 de abril de 2014, relativo a las medidas de cumplimiento de los usuarios del Protocolo de Nagoya sobre el acceso a los recursos genéticos y participación justa y equitativa en los beneficios que se deriven de su utilización en la Unión, la solicitud de patente deberá asimismo contener, en la medida en que reglamentariamente se determine, la información que los usuarios de tales recursos vienen obligados a conservar con arreglo a lo previsto en la norma citada . La referida información tampoco prejuzgará la validez de la patente.	de Nagoya sobre el acceso a los recursos genéticos y participación justa y equitativa en los beneficios que se deriven de su utilización en la Unión, la solicitud de patente deberá asimismo contener, en la medida en que reglamentariamente se determine, la información que los usuarios de tales recursos vienen obligados a conservar con arreglo a lo previsto en la norma citada. La referida información tampoco prejuzgará la validez de la patente.
Sweden	Regulation (2004:162) Amending the Patents Decree (<u>http://www.wipo.int/wipolex/en/details.jsp?id=3672</u>)	Article 5a biological material of plant or animal origin	Article 5a. If an invention concerns biological material of plant or animal origin or if it uses such material, the patent application shall include information on the geographical origin of such	Article 5a. If an invention concerns biological material of plant or animal origin or if it uses such material, the patent application shall include information on the geographical origin	Article 5a. If an invention concerns biological material of plant or animal origin or if it uses such material, the patent application shall include information on the geographical origin of such material, if this is known. If the

			material, if this is known. If the origin is not known, this shall be indicated. Lack of information on the geographical origin or on the knowledge of the applicant regarding the origin is without prejudice to the processing of the patent application or the validity of the rights arising from a patent granted.	of such material, if this is known. If the origin is not known, this shall be indicated. Lack of information on the geographical origin or on the knowledge of the applicant regarding the origin is without prejudice to the processing of the patent application or the validity of the rights arising from a patent granted.	origin is not known, this shall be indicated. Lack of information on the geographical origin or on the knowledge of the applicant regarding the origin is without prejudice to the processing of the patent application or the validity of the rights arising from a patent granted.
Switzerland	Federal Act of June 25, 1954 on Patents for Inventions (status as of April 1, 2019) (https://www.wipo.int/wipolex/en/legislation/details/18795)	Article 49a Genetic resource; traditional knowledge of indigenous or local communities	Article 49a 1. The patent application must contain information on the source: a. of the genetic resource to which the inventor or the patent applicant had access, provided the invention is directly based on this resource; b. of traditional knowledge of indigenous or local communities to which the inventor or the patent applicant had access, provided the invention is directly based on this knowledge.	Article 49a 1. The patent application must contain information on the source: a. of the genetic resource to which the inventor or the patent applicant had access, provided the invention is directly based on this resource; b. of traditional knowledge of indigenous or local communities to which the inventor or the patent applicant had access, provided the invention is directly based on this knowledge. 2. If the source is unknown to the	Article 59 [] 2. If the patent application does not meet the other requirements of this Act or the Ordinance, the Institute shall set a time limit for the patent applicant by which the deficiencies must be remedies. Article 59(a) 3. The Institute shall reject the patent application if: [] b. the deficiencies mentioned in Article 59 paragraph 2 have not been remedied. Art. 81a 1. Any person who wilfully provides false

				inventor or the patent applicant, the patent applicant must confirm this in writing.	 information under Article 49a is liable to a fine of up to 100,000 francs. 2. The court may order the publication of the judgment.
Uganda	The Industrial Property Act, 2014 https://wipolex.wipo.int/en/legislation/details/16480	21. Application for a patent. [] (8) biological resources, traditional knowledge	21. Application for a patent. [] (8) The description shall contain a clear identification of the origin of genetic or biological resources collected in the territory of Uganda and that were directly or indirectly used in the making of the claimed invention as well as of any element of traditional knowledge associated or not with those resources and that was directly or indirectly used in the making of the claimed invention without the prior informed consent of its individual or collective creators.	21. Application for a patent. [] (8) The description shall contain a clear identification of the origin of genetic or biological resources collected in the territory of Uganda and that were directly or indirectly used in the making of the claimed invention as well as of any element of traditional knowledge associated or not with those resources and that was directly or indirectly used in the making of the claimed invention with those	Section 90 [] (3) The court shall revoke or invalidate the registration of the patent or the utility model or industrial design on any of the following grounds that— [] (f) the patent does not fully describe and ascertain the invention and the manner in which it is to be performed;
Vanuatu	Patents Act No. 2 of 2003 (http://www.wipo.int/wipolex/en/details.jsp?id=10727)	PART 12 INDIGENOUS KNOWLEDGE	PART 12 INDIGENOUS KNOWLEDGE	PART 12 INDIGENOUS KNOWLEDGE	PART 12 INDIGENOUS KNOWLEDGE

		REGISTRATION OF PATENT INVOLVING INDIGENOUS KNOWLEDGE 47. [] Indigenous knowledge []	REGISTRATION OF PATENT INVOLVING INDIGENOUS KNOWLEDGE 47. [] (2) The Registrar must not grant a patent for an invention that is based on, arose out of, or incorporates elements of, indigenous knowledge unless: (a) the custom owners of the indigenous knowledge have given their prior informed consent to the grant; and (b) the applicant and the custom owners have entered into an agreement on the payment by the applicant to the custom owners of an equitable share of the benefits from exploiting the patent.	REGISTRATION OF PATENT INVOLVING INDIGENOUS KNOWLEDGE 47. [] (2) The Registrar must not grant a patent for an invention that is based on, arose out of, or incorporates elements of, indigenous knowledge unless: (a) the custom owners of the indigenous knowledge have given their prior informed consent to the grant; and (b) the applicant and the custom owners have entered into an agreement on the payment by the applicant to the custom owners of an equitable share of the benefits from exploiting the patent.	REGISTRATION OF PATENT INVOLVING INDIGENOUS KNOWLEDGE 47. [] (4) If an agreement mentioned in subsection (2) or (3) has not been entered into within 12 months after the patent application has been lodged: (a) the Registrar may grant the patent; and (b) the owner may exploit the patent; and (c) the Registrar is to determine the amount payable to the custom owners or the National Council of Chiefs by the owner of the patent, being payment of an equitable share of the benefits from exploiting the patent.
Viet Nam	Circular No. 01/2007/TT-BKHCN of February 14, 2007, guiding the Implementation of the Government's Decree No. 103/2006/ND-CP of September 22, 2006, detailing and guiding the Implementation of a Number of Articles of the Law on Intellectual Property regarding Industrial Property (http://www.wipo.int/wipolex/en/details.jsp?id=5013)	Article 23.11 Gene source and/or traditional knowledge	Article 23.11 Additional provisions applicable to applications for registration of inventions concerning gene source or traditional knowledge	Article 23.11 Additional provisions applicable to applications for registration of inventions concerning gene source or traditional knowledge	Article 23.11 [] If the inventor or the applicant cannot identify the origin of the gene source and/or traditional knowledge, he/she shall so declare and bear responsibility for the

			Apart from the general requirements for invention registration applications specified at Points 23.1 thru 23.7 of this Circular, an application for registration of an invention concerning gene source or traditional knowledge must also contain documents explaining the origin of the gene source and/or traditional knowledge accessed by the inventor or the applicant, if the invention is directly based on that gene source and/or traditional	Apart from the general requirements for invention registration applications specified at Points 23.1 thru 23.7 of this Circular, an application for registration of an invention concerning gene source or traditional knowledge must also contain documents explaining the origin of the gene source and/or traditional knowledge accessed by the invention is directly based on that gene source and/or traditional	truthfulness of his/her declaration
Zambia	The Patents Act, 2016 (Act No. 40 of 2016) (https://wipolex.wipo.int/en/legislation/details/18207)	28. [] invention which utilises genetic resources or associated traditional knowledge or both []	knowledge. [] 28. Where an application for the grant of a patent involves an invention which utilises genetic resources or associated traditional knowledge or both, the applicant shall disclose — (a) the country of origin of the genetic	knowledge. [] 28. Where an application for the grant of a patent involves an invention which utilises genetic resources or associated traditional knowledge or both, the applicant shall disclose — (a) the country of origin of the genetic resources or associated	PART V Examination, publication and opposition 51. [] (3) Where the Registrar is of the opinion, after conducting an examination, referred to in subsection (1), that an application is not compliant with the requirements of this Act, the Registrar shall

associated knowledge in writing, to make traditional knowledge in accordance with accordance with amendments to in accordance with the Convention on Bio-Diversity; and (b) the source in the country providing the genetic resources grasticitad genetic resources providing the subsection (3), or associated traditional knowledge. writing, refuse amendments, ti knowledge. fraditional genetic resources providing the subsection (3), writing, refuse fraditional knowledge. mendments, ti knowledge. fraditional Registrar shall, knowledge. fraditional knowledge. amendments, ti fraditional knowledge. fraditional knowledge. amendments, ti fraditional knowledge. amendments, ti fraditional mendments, ti knowledge. fraditional knowledge. amendments, ti fraditional mendments, ti knowledge. fraditional knowledge. amendments, ti fraditional knowledge. amendments, ti	the hin a bd. upplicant rred to in make he in the he cluding oppose patent at
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country providing the genetic resources or associated traditional knowledge.the country providing the genetic resources or associated traditional knowledge.notification refe subsection (3), the relevant amendments, the Registrar shall, writing, refuse application. [] 56. A person, in the State, may the grant of a	rred to in make ne in the ncluding oppose patent at
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The Protection of Traditional Knowledge, Genetic Resources and Expressions of Folklore Act, 2016 (Act No. 16 of 2016) (https://wipolex.wipo.int/en/legislation/details/16181)	36. [] product developed from the genetic resource []	36. An access permit holder shall have the following obligations: [] (I) recognise the locality where the genetic resource or traditional knowledge has been accessed in an application for protection of the product developed from the genetic resource; []	36. An access permit holder shall have the following obligations: [] (I) recognise the locality where the genetic resource or traditional knowledge has been accessed in an application for protection of the product developed from the genetic resource; []	
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