

SUMMARY TABLE OF NATIONAL DOO* LAWS

*DISCLOSURE OF ORIGIN OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE

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(Additional information can be found at <http://www.wipo.int/tk/en/laws/genetic.html>)

Country	Law	Disclosure Requirements	When is Disclosure Required?	Sanctions for Failure to Comply	Comments
Andean Community (Bolivia, Colombia, Ecuador, Peru)	Decisions 391, 486, 523	- If there is reason to believe that a genetic resource originated in a member country, the National patent authority must require applicant to provide the registration No. and copy of access contract.	- When requested by national patent authority. - Request for access to genetic resource generally must precede access.	Revocation of patent rights / inability to obtain a patent.	Andean Community Decisions have direct legal force in member countries. See also Peru law 27811 re permitting.
Belgium	Patent Law of 1984, Art. 5	- Applications must contain the geographic source of the plant or animal material, if known, that formed the basis for the development of the invention	Upon filing	None within patent law.	- Requirements apply only to applications filed directly in Belgium, not to PCT- or EP-based applications.
Brazil	Provisional Measure No. 2.186-16/01, PTO Resolution No. 134 (Dec. 2006)	- Declaration regarding whether subject matter of application was obtained as a result of access to Brazilian genetic heritage and/or associated traditional knowledge; - Prior authorization (see Comments)	Upon filing	<u>For failure to satisfy duty of disclosure requirements:</u> Nullity or suspension of patent <u>For failure to satisfy pre-authorization requirements:</u> - Seizure of end products - Fines up to USD 20mil - Prison term (pending bill)	- Also required: pre-authorization of access from Genetic Heritage Management Council (CGEN) - Access is only available to Brazilian entities or international joint ventures coordinated by local entities - Access requires written previous consent from: -- if private area: owner of land -- if indigenous land: community and Indian Affairs body.

This table is informational and is not intended as legal advice. Consult qualified counsel regarding the state of the law in each country.

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China	Arts. 5(2), 26(5) (As amended 12/27/08; changes effective 10/1/09)	Disclosure of direct and original source of any genetic resources; or applicant must provide reasons why source cannot be provided (Art 26(5))	Unclear, though appears to be required upon filing	Violation of Art. 5: inability to obtain patent Violation of Art. 26: Unclear	-Per Art. 5(2): no patent will be granted on any invention that depends on genetic resources for its completion if the acquisition or exploitation of the genetic resources violates any of China's laws or regulations. - Other laws relate to traditional knowledge / biodiversity
Costa Rica	Biodiversity Law 7788 (1988) Art. 80	- Patent office must consult with biodiversity commission; certificate of origin and prior informed consent required before granting patents "involving components of biodiversity" (Art 80)	NA	Violation of Art. 80: unclear	- Text unclear as to whether duty to disclose is on agency or applicant.
Denmark	Patents Decree, Ch. 2, Art. 3, Section 4	Disclosure of geographical origin of biological material of animal or vegetable origin.	Upon filing	None – no effect on "assessment of the patent application or the validity of the rights resulting from the granted patent."	- If applicant does not have knowledge of origin of biological material, this must be stated in application.
Egypt	Law on the Protection of Intellectual Property Rights (Law No. 82), Article 13	Applicant must have acquired any biological product or traditional knowledge "in a legitimate manner."	NA	Unclear	
India	Patent (Amendment) Ordinance, 2004, Section 25	Disclosure of source and geographical origin of biological material used in the invention	Upon filing	Application is subject to opposition after publication up until 1 year after grant.	Application is also subject to opposition after publication but prior to grant on grounds that it is anticipated by the knowledge of an indigenous community in India or elsewhere. <u>The following are not inventions:</u> - Plants and animals in whole or any

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					part thereof other than micro-organism but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals. - An invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known compounds or components.
	Sec. 6 of Biodiversity Act, 2002:			it is a criminal act (punishable by fine or imprisonment) to apply for IP right in or outside India for any invention based on research or information on a biological resource from India without prior approval from National Biodiversity Authority	
Norway	Patent Law, Article 8(b)	<ul style="list-style-type: none"> - For biological material, disclosure of providing country. - If country of origin is different from providing country, must also disclose country of origin. - If providing country or country of origin requires prior consent for access, then application must state whether consent has been obtained. - If origin or provider is not known, this must be stated. 	Upon filing	<ul style="list-style-type: none"> - Does not affect processing of applications or validity of patent rights. - But punishable under General Civil Penal Code § 166 (which provides for fines or imprisonment up to 2 years). Treated as false testimony to a public authority. 	<p>These requirements do not apply to biological materials obtained from the human body.</p> <p>PCT applications are exempt from these requirements.</p>

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South Africa	Patents Amendments Act 20 of 2005	Completion of Form P26, which requires Applicant to state whether the claimed invention is based on or derived from indigenous biological resource, genetic resource, or traditional knowledge; and if it is co-owned by a local community or individual; - If the invention is based on biological or genetic resources or traditional knowledge, must submit proof of authority to use (see Comments)	Within 6 months of filing application	<u>Failure to submit Form P26:</u> inability to obtain patent. <u>False statement:</u> If material, and the applicant knew or should have known of falsity, then patent can be revoked.	- The requirements only apply to South African resources or traditional knowledge. - Form P26 does not have to be completed for provisional applications. Authority to make use of the resource / traditional knowledge must be established under Chapter 7 or Section 82 of the South African Biodiversity Act of 2004.
Sweden	Patents Decree, Article 5(a)	For inventions that relate to biological material from plants or animals, the application should include information on the geographical origin of the material.	NA (see Sanctions, Comments)	Unsanctioned. Does not affect examination of patent applications or validity of patent rights.	There is no set procedure regarding manner of compliance. I.e., not required to be in application, and Sweden does not require any particular form to be submitted.

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Switzerland	Swiss Patent Law Arts. 49(a), 59, 81(a), 138	The application shall contain information on the source of a genetic resource, or traditional knowledge of indigenous or local communities related to genetic resources, to which the inventor or the patent applicant has had access, insofar as the invention is directly based on this resource / knowledge. If not known, the patent applicant shall confirm this in writing.	Within 30 months of the filing date or priority date. If applicant fails to comply, the Federal Institute of Intellectual Property will give a period of time for correction. If not corrected in that time, the application will be rejected.	For failure to comply with requirement: application will be rejected, and it will be impossible to get a patent. For intentionally making a wrongful declaration: fine of up to 100,000 Swiss francs.	

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