



PATENT DISCLOSURE REQUIREMENTS FOR GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE: NATIONAL REGULATIONS IN SELECT WIPO MEMBER STATES

This document presents the key elements of patent disclosure requirements (PDR) for genetic resources (GR) and associated traditional knowledge (TK) in select WIPO Member States' national laws. As shown in the chart below, patent applicants currently face a mosaic of different rules in relation to the mandatory disclosure of GR and associated TK that relate to their inventions. As confirmed by WIPO, more than 30 developing and developed countries already have or are in the process of creating a PDR in their national laws. The requirements and legal consequences for disclosures that are deemed incomplete differ substantially from country to country.

According to patent owners, differences in PDR requirements across jurisdictions can create substantial compliance challenges, costs, and legal uncertainty. In some cases, the requirements may be unduly burdensome for innovators, especially in cases where issues with disclosure can block the granting of patents or lead to their revocation.

To commit financial and other resources to R&D and commercialization, with a timeframe of 10 – 20 years or more, companies and other innovative organizations require certainty and stability. Patents are important tools for managing investments and collaboration throughout R&D and commercialization. If patents become harder to obtain for natural resource-related inventions – more costly, subject to undue delays or burdensome administrative requirements, and with more uncertain protection – innovators may shift resources away from natural resources R&D programs.

For innovators, differences in patent disclosure requirements can influence decision-making about where to site R&D, work with partners, and commercialize natural resource-related inventions, with investments declining in or moving away from countries with relatively burdensome PDRs.

R&D involving non-human genetic resources has been under pressure in recent years, due to various factors including greater inherent complexities of natural substances and thereby greater challenges in analyzing, synthesizing, and modifying such substances to develop new products. In the field of biopharmaceutical research, for example, anecdotal evidence points to such programs steadily receiving fewer resources and less attention within innovative organizations over time. They will undoubtedly be further de-prioritized if it becomes more difficult to secure and maintain patent protection for the relevant R&D outcomes. Innovators across sectors have warned of this possibility, which would undermine the goal of encouraging innovation that leverages GR and associated TK.

Table: Comparison of Patent Disclosure Requirements for GRs and a TK in Select WIPO Member States

State	Covered Subject Matter	TK Defined?	Information Subject to Disclosure	Disclosure to be Made in the Patent Application?	"Geographical Origin" / "Source" Defined?	Consequences of Noncompliance
Germany	GR	N/A	Geographical origin.	Yes	No	None
France	GR and TK	Yes (via EU Regulation 511/2014)	Information maintained pursuant to EU Regulation 511/2014 ¹	No (to INPI instead)	N/A (but the "source" from which GR/TK was "directly obtained" is not defined in EU Regulation 511/2014)	None
Spain	GR and TK	Yes (via EU Regulation 511/2014)	"Geographical origin or source" plus information maintained pursuant to EU Regulation 511/2014	Yes	No ("source" from which GR/TK was "directly obtained" is not defined in EU Regulation 511/2014)	None
Italy	GR	N/A	Country of origin and "the biological organism from which (the GR) was isolated."	Yes	Specified to refer to the country of origin and the biological organism from which the GR was isolated.	General noncompliance: refusal to grant the patent on the basis of the application False statements: civil fines.
Norway	GR and TK	No	Information on the provider country/country of origin, and evidence of PIC (if required by provider/country of origin's law)	Yes	N/A (but "country of origin" is defined)	Penalties provided for under GCPC § 221 (at least for affirmative falsehoods).
Turkey	GR and TK	No	Geographical "roots" (if known) or where the GR/TK was taken from (if geographical "roots" not known)	Yes	No	Refusal to grant the patent on the basis of the application.

¹EU Regulation 511/2014 defines "traditional knowledge associated with genetic resources" as "traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is as such described in the mutually agreed terms applying to the utilisation of genetic resources." The same EU Regulation highlights that "[t]here is currently no internationally-agreed definition of 'traditional knowledge associated with genetic resources'.

State	Covered Subject Matter	TK Defined?	Information Subject to Disclosure	Disclosure to be Made in the Patent Application?	"Geographical Origin" / "Source" Defined?	Consequences of Noncompliance
Brazil	GR and TK	Yes	(1) GR: "source and geographical origin" (2) TK from identified origin: "source and geographical origin" and traditional owner's prior consent (3) TK from unidentified origin: nothing* *all requirements are expounded upon in implementing regulation	No (in access registration instead)	Not directly, but the regulations indicate that highly precise geographical information (i.e. coordinates) must be disclosed	Refusal to grant the patent on the basis of the application, and possible civil fines.
China	GR	N/A	"Direct and original source"	Yes	No	Refusal to grant the patent on the basis of the application.
India	GR	No	"Source and geographical origin"	Yes (in specification)	No	Refusal to grant the patent on the basis of the application, or revocation of the patent (plus fines or prison time for violating Article 6 of the Biological Diversity Act).
Indonesia	GR and TK	No	"Origin"	Yes	No	Refusal to grant the patent on the basis of the application, or revocation of the patent.
S. Africa	GR, TK and "indigenous biological resources"	Yes	Declaration of use in an invention, and evidence of PIC and MAT (proof of use-rights); unclear if disclosure of source/origin is specifically required	Yes (in Section 30(3A) Statement)	No	Revocation of the patent [for false statements and material misrepresentations in the Section 30(3A) Statement]; unclear whether nondisclosure of source/origin would result in refusal to grant the patent on the basis of the application.



Innovation Council

We promote enabling policies
for innovation and
technology diffusion.

Contact us

information@innovationcouncil.org

Learn more

innovationcouncil.org