



**Examination Guidelines on
Patents, Utility Models, and Designs involving
Biodiversity, Genetic Resource (GR), Traditional
Knowledge (TK), Traditional Cultural Expressions (TCE),
and Indigenous Knowledge, Systems and Practices (IKSP)**

INTRODUCTION

The objective of this internal document is to guide Examiners on how to handle and treat applications with involve biodiversity, genetic resource (GR), traditional knowledge (TK), traditional cultural expressions (TCE), and indigenous knowledge, systems and practices (IKSP).

The purpose is to align Bureau practices with international treaties, relevant Philippine laws. The Bureau recognizes and supports the objectives of the Philippine government in ensuring:

1. The enhanced efficacy, transparency and quality of the patent, utility model, and industrial design system with regard to biodiversity, GR, TK, TCE, and IKSP;
2. That no patents or utility model registrations are granted erroneously for inventions that are not novel or inventive with regard to biodiversity, GR, TK, TCE, and IKSP;
3. That no design registrations are granted erroneously for designs that are not novel with regard to biodiversity, GR, TK, TCE, and IKSP.

Under various international treaties and relevant Philippine laws, the Bureau of Patents serves as a checkpoint and collecting office whereby relevant disclosed information is collected and the information is referred to the National Commission on Indigenous Peoples (NCIP), Department of Energy and National Resources (DENR), Department of Agriculture (DA), or other identified Government Funding Agency (GFA) as the case may be, for the verification by these agencies.

Notable relevant documents include Republic Act 10055 (or the Technology Transfer Act of 2009), the IRR of 10055, Republic Act 8371 (or the Indigenous Peoples' Rights Act of 1997 IPRA), the Convention on Biodiversity (CBD), Nagoya Protocol, the Joint IPOPHL-NCIP Administrative Order No. 01, 2016 (JAO IPOPHL-NCIP), among others. Further, there are ongoing multilateral negotiations at the WIPO-Inter Governmental Committee to come up with international treaties on a) Genetic Resources and its associated Traditional Knowledge, and b) Traditional Knowledge and Traditional Cultural Expressions, both of which will place certain duties upon patent offices, if it comes becomes a binding international instrument.

The Bureau and its Examiners do not verify or vet such information since doing so is beyond its mandate, knowledge, and skill. However, the Bureau and its Examiners have the duty and obligation to properly construe if biodiversity, GR, TK, TCE, and IKSP are indeed used in the invention, utility model, or design.

It is the Bureaus hope that these Guidelines provide direction and clarity to a relevant area of interest that intersects directly with creations and innovations.



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Director, Bureau of Patents

Scope of these Guidelines

The foregoing guidelines shall apply equally to all applications that are filed before the Bureau. Likewise, these shall also apply equally whether the actual or particular biodiversity, GR, TK, TCE, and IKSP is sourced from the Philippines or elsewhere.

Definition of Terms¹

Biological resources - includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

Biotechnology – any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use(Nagoya Protocol)

Community Intellectual Rights - Community Intellectual Rights refer to the rights of the indigenous peoples and indigenous cultural communities to own, control, develop, and protect:

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(b) science and technology including, but not limited to, human and other genetic resources, seeds, medicine, health practices, vital medicinal plants, animals, and minerals, indigenous knowledge systems and practices, vital medicinal plants, animals and minerals, indigenous knowledge systems and practices, resource management systems, agricultural technologies, knowledge of the properties of fauna and flora, oral traditions, designs, scientific discoveries;

Free and Prior Informed Consent - refers to the consensus of the members of the indigenous cultural communities to be determined in accordance with their respective customary laws and practices, free from external manipulation, interference, and coercion, and obtained after fully disclosing the intent and scope of the activity, in a language and process understandable to the community.

Genetic Resources - means genetic material of actual or potential value (Convention on Biological Diversity)

- May also refer to Genetic and other biological resources include microorganisms, plant varieties, animal breeds, genetic sequences, nucleotide, and amino acid sequence information, traits, molecular events, plasmids, and vectors (WIPO)

Indigenous Knowledge Systems and Practices - refer to systems, institutions, mechanisms and technologies 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 environment, including such spheres of relationships which may include social, political, cultural, economic, religious

¹ References to definitions may be sought from: TTA (10055), IRR of 10055, IPRA, NCCA, CBD, Nagoya, JAO IPOPHL-NCIP, JAO DOST-IPOPHL, draft GRTK and TKTCE IGC documents, ITPGRFA

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 (section 1 (p), Rule II, NCIP Administrative Order No. 1, series of 1998).

- The definitions of traditional knowledge and traditional cultural expressions emanate from the aforementioned definition and are included in the said unique body of knowledge

Based on - means that the GR, TK, TCE, and IKSP is either essential or indispensable to the development of the claimed invention; or necessarily relating to, derived from, or consisting of the specific properties of the GR, TK, TCE, and IKSP²

Traditional Knowledge Associated with Genetic Resources (or associated TK) – refers to IKSP information about that particular GR

Mandatory Disclosure

In accordance with the directives of RA 10055 and its IRR, Joint DENR-DA-PCSD-NCIP Administrative Order No. 1, series of 2005 (JAO DENR-DA-PCSD-NCIP), IPRA, and JAO IPOPHL-NCIP it appears that the Philippine government has adopted a mandatory disclosure regime wherein potential intellectual property rights **directly or materially using** biodiversity and GR, and/or **using** TK, TCE, and IKSP must be reported by the applicant.

For Examiners, it bears noting that the concept of mandatory disclosure of biodiversity, GR, TK, TCE, and IKSP is separate from, but related to, the concept of enabling disclosure in patent practice. Mandatory disclosure herein refers to the making known, by the applicant, if biodiversity, GR, TK, TCE, and IKSP was used in the application. Information contained in the mandatory disclosure may or may not be relevant in determining if a claim has sufficient enabling disclosure or sufficient support in the patent description

Disclosure in the Application Form

Pursuant to this, the downloadable PDF application forms for patents, utility models, and industrial designs require the applicant to disclose the following:

- a. If the invention is based on GR and a TK;
- b. If the design is based on TK, TCE, or IKSP;
- c. The country of origin or source of biodiversity, GR, TK, TCE, and IKSP; and
- d. Presence or absence of FPIC.

If any of these are disclosed, the applicant must disclose where the biodiversity, GR, TK, TCE, and IKSP used in the application was sourced and / or country of origin.

If biodiversity, GR, TK, TCE, and IKSP is disclosed by the applicant, the applicant must further disclose if FPIC was secured. Acceptable proof includes a certification

² Refer to definition of “direct” in <https://www.merriam-webster.com/dictionary/direct#dictionary-entry-2>

from the NCIP, DENR, DA, NCCA, identified GFA, as the case may be. This shall form part of the File Wrapper history of the patent application.

If the invention or design does not utilize biodiversity, GR, TK, TCE, and IKSP, then the applicant should submit a negative Self-Declaration to that effect.

The Examiners must note that as of the writing of these guidelines, the **online** application forms still do not contain such entry fields. However, the Bureau has provided a template **AFFIDAVIT / SELF-DECLARATION**³ which applicants must use for the said mandatory disclosure undertaking.

The Examiner is thus directed to be alert when reading the specification and construing the description and claims as these may contain information regarding biodiversity, GR, TK, TCE, and IKSP that may or may not have been overtly disclosed in the application form.

Explicit Disclosure in the Application Form

If there is explicit disclosure in the application form, the Examiner is instructed to immediately and directly inform the Office of the Director and the respective Division Chief of the following.

1. Application number
2. Title of the application
3. Identity of the applicant
4. Identity and nature of the biodiversity, GR, TK, TCE, and IKSP
5. Source of the biodiversity, GR, TK, TCE, and IKSP, whether these be a country, a locality, an IPLC, and the like, and
6. Presence or absence of FPIC

Absence of Explicit Disclosure in the Application Form

In the event that the application form does not contain explicit disclosures, the Examiner is directed to be alert when reading and construing the description and claims as these may contain information regarding biodiversity, GR, TK, TCE, and IKSP that may or may not have been overtly disclosed in the application form.

If there is no disclosure of biodiversity, GR, TK, TCE, and IKSP in the application form but the Examiner identifies its existence through the description or claims, the Examiner is instructed to still immediately and directly inform the Office of the Director and the respective Division Chief.

Trigger for Disclosure or Construing the Subject Matter

The IRR of R.A. 10055 state that biodiversity, GR, TK, TCE, and IKSP must be disclosed and are relevant if it is “**utilized in or which formed as basis**”⁴ the subject

³ Attached as Annex 1

⁴R.A. 10055 IRR, also known as Joint DOST-IPOPHL Administrative Order No. 02-2010

matter contained in the application. The disclosure or non-disclosure shall apply to all applications. It shall also apply when the subject matter is based on any biodiversity, GR, TK, TCE, and IKSP. The subject matter must depend on the specific properties of, or must be consciously derived from, such biodiversity, GR, TK, TCE, and IKSP. Notably, R.A. 10055 currently applies only to intellectual property generated from research and development funded wholly or partly by the Philippine government.

The JAO IPOPHL-NCIP states that disclosure shall be done if the associated TK, TCE, and / or IKSP is “**used**” in the patent, utility model, or design.

For guidance of the Examiner, the terms “utilized”, “forms as basis”, “used”, “directly” and “materially” shall be understood in a broad sense. Thus, the biodiversity, GR, TK, TCE, and IKSP might be the subject matter of the claim / invention, it might be a raw or direct material, it might be the source of isolated genetic material, or the source of the pharmaceutical compound.

The Examiner should further note that TK, TCE, and IKSP might be mentioned in the description as the inspiration or source of information which led the inventor to perform research which led to the invention. Considering the liberal interpretation of the term “used” and the strict intention of Philippine public policy in relation to protecting biodiversity, GR, TK, TCE, and IKSP, any doubt in mind of the Examiner if biodiversity, GR, TK, TCE, and IKSP is used should be resolved in the affirmative.

Information to be relayed to relevant agencies

The Office of the Director shall inform the relevant agencies of the following:

1. Identity of the applicant
2. Identity and nature of the biodiversity, GR, TK, TCE, and IKSP
3. Source of the biodiversity, GR, TK, TCE, and IKSP, whether these be a country, a locality, an IPLC, and the like
4. Presence or absence of FPIC

No other information regarding the invention or design shall be made known to the relevant agencies until the 18-month confidentiality period has lapsed or the application undergoes 1st publication, whichever comes first. This is to ensure fidelity to the requirements of confidentiality before 1st publication.

Treatment of the biodiversity, GR, TK, TCE, and IKSP Disclosure in Patent Prosecution

While the Bureau is waiting for verification of the information relayed to relevant agencies, it shall not halt the examination process.

The Examiner is directed to analyze both the claims and the description to determine if there seems to be a related or used biodiversity, GR, TK, TCE, and IKSP. They are further directed to check the various listed databases and sources and treat the disclosed biodiversity, GR, TK, TCE, and IKSP as additional information in

determining patentable subject matter, support and enablement, clarity, novelty, and inventive step.

Determination of patentable subject matter, support and enablement, clarity, novelty, and inventive step in applications using biodiversity, GR, TK, TCE, and IKSP is the same as regular applications. This will be the standard practice until the Philippines decides to become or not become a signatory to international treaties or will issue local laws that will require a different treatment.

If, in the course of the prosecution, the Examiner believes it is important to get additional information from the relevant clearing house agencies in determining if the application should grant the patent, the Examiner shall discuss the matter with the Office of the Director and the Division Chief so that a formal request may be directed to the relevant agencies.

Further, the Examiner may, at any point in the substantive examination, may refer to the NCIP, through the Office of the Director, any concerns pertaining to the disclosure of the subject patent examination.

Do note that there is much ongoing discussion in the international policy arena, particularly at the WIPO – IGC on how disclosure information should be treated. These guidelines may be eventually revised, depending on future developments.

Effect of Non-Disclosure

Under the JAO IPOPHL-NCIP, non-disclosure on the part of the applicant that an application involves TK, TCE, and IKSP or failure to obtain FPIC is a basis for “effecting” registration⁵. In short, it is not currently a ground to deny or reject the application. However, the Examiner will suspend the granting of the application until such time the applicant submits an Affidavit disclosing the relevant TK, TCE, and IKSP information and submits an FPIC verified by the NCIP. It is akin to the applicant complying with the Completion of Final Requirements

Refusal by the NCIP with respect to the issuance of the required verification, or a negative verification shall likewise cause the indefinite suspension of the said application grant.

Notably the IRR of R.A. 10055 requires disclosure of biodiversity, GR, TK, TCE, and IKSP but is silent on the effect of non-disclosure.

Should a non-disclosure scenario exist and the application is in the final stages of the prosecution wherein disclosure of biodiversity, GR, TK, TCE, and IKSP and FPIC is the only pending matter, the Examiner should report to the concerned Division

⁵Rule 6.d. The registration for an intellectual property right that uses IKSP in the subject matter of the 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 issued in violation of these Rules and Regulations, the IPOPHL may, in accordance with its rules and regulations, cancel the registration.

Chief and the Office of the Director before issuing an office action informing the applicant of such suspension.

Effect of Misrepresentation

The JAO IPOPHL-NCIP does not impose an obligation on the Bureau in the event misrepresentation becomes apparent during the prosecution of the application but the concerned third-party or relevant government agency may seek available legal remedies available to it. A concerned third-party may also file Third-Party Observations and Adverse Information.

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REPUBLIC OF THE PHILIPPINES)
PROVINCE OF _____) : SS
CITY OF _____)

AFFIDAVIT / SELF-DECLARATION

I, _____, of legal age, [INSERT CITIZENSHIP], and a resident of _____, after having been duly sworn to in accordance with law hereby depose and say:

That I am the inventor / owner [INDICATE APPROPRIATE DESIGNATION] of patent application no. _____; a product/process based on Genetic Resources and Traditional Knowledge associated with Genetic Resources (GRaTK).

That to the best of my knowledge, the country of origin of the said genetic resource is _____ [INSERT COUNTRY OF ORIGIN; IF COUNTRY OF ORIGIN IS UNKNOWN, STRIKE OUT THIS PARAGRAPH AND USE THE ONE BELOW].

That I am not aware of the country of origin of the said genetic resource but that I have actually obtained and sourced the said genetic resource from _____ [INSERT LOCATION OR PLACE FROM WHERE THE GENETIC RESOURCE WAS TAKEN].

That the traditional knowledge associated with the genetic resource was provided by _____ [IDENTIFY THE INDIGENOUS PEOPLES OR LOCAL COMMUNITY THAT PROVIDED THE INFORMATION] and it was obtained with their Free Prior and Informed Consent.

I hereby declare that this patent application is not a product used or misused by others earning the exclusive rights for patenting said product/s;

That I am executing this affidavit to attest to the truthfulness of the foregoing and for all legal intents and purposes;

IN WITNESS WHEREOF, I have hereunto set my hands this ____ day of Month, ____ in the City of _____, Province, Philippines.

Affiant
ID No.

SUBSCRIBED AND SWORN to before me this ____ day of Month, year in the City of _____, Province, Philippines.

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