

Philippine Group

Prefatory Statement

Some of the answers to the questions were taken from the Answers of the Philippine Group to Question 166 prepared by Mr. Bienvenido Somera. The other answers were supplied by the undersigned reporter.

1. Is there a legal requirement in your country that the source and/or country of origin of biological resources and traditional knowledge must be indicated in patent application for inventions based on such biological/genetic resources or traditional knowledge?

Answer: Yes, Specifically, Section 26.1 of the Joint DENR-DA-PCSD-NCIP Administrative Order No. 1, Series of 2005 (“DENR-DA-PCSD-NCIP 2005”) states:

Section 26. Overseas monitoring

26.1 The implementing agencies may seek the assistance of the Department of Foreign Affairs (“DFA”) and Department of Science and Technology in monitoring inventions and commercialization undertaken in foreign countries. These Departments shall be notified in writing by the implementing agencies about Bioprospecting Undertakings(“BU”) with foreign entities. The DFA, through its Embassies and Missions abroad, is encouraged to report to the implementing agencies any breach of the BU. In particular, the DFA is encouraged to make representations with concerned foreign authorities particularly on the following aspects:

- a) Prevention of biological resources from entering countries without a BU;
- b) Requiring disclosure of country of origin (CO) and presentation of BU in patent applications;**
- c) Facilitation of enforcement of claims against collectors or commercializing entities.

Indirectly, the following laws require the acknowledgement of indigenous people in writings or data as a result or research. They are as follows:

1. Rule VI, Section 15 of the implementing rules of Republic Act No. 8371, otherwise known as the Indigenous Peoples’ Rights Act of 1997 (“IPRA”), provides:

Section 15. Protection and Promotion of Indigenous Knowledge Systems and Practices (IKSPs). The following guidelines, inter alia, are hereby adopted to safeguard the rights of IPs to their indigenous knowledge systems and practices:

- a) The ICCs/IPs have the right to regulate the entry of researchers into their ancestral domains/lands or territories. Researchers, research institutions, institutions of learning, laboratories, their agents or representatives and other like entities shall secure the free and prior informed consent of the ICCs/IPs, before access to indigenous peoples and resources could be allowed;
- b) A written agreement shall be entered into with the ICCs/IPs concerned regarding the research, including its purpose, design and expected outputs;
- c) All data provided by the indigenous peoples shall be acknowledged in whatever writings, publications, or journals authored or produced as a result of such research. The indigenous peoples will be definitively named as sources in all such papers;**
- d) Copies of the outputs of all such researches shall be freely provided the ICC/IP community; and
- e) The ICC/IP community concerned shall be entitled to royalty from the income derived from any of the researches conducted and resulting publications.

To ensure effective control of research and documentation of their IKSPs, the IPOs' initiatives in this regard shall receive technical and financial assistance from sources of their own choice.

2. Executive Order No. 247 ("EO 247") dated 18 May 1995, provides for the regulatory framework for the prospecting of biological and genetic resources for scientific and commercial purposes. In its whereas clause, it is enunciated:

WHEREAS, it is in the interest of the State's conservation efforts to ensure that the research, collection and use of species, genes and their products be regulated; and to identify and recognize the rights of indigenous cultural communities and other Philippine communities to their traditional knowledge and practices when this information is directly and indirectly put to commercial use.

3. Rule IX of the implementing rules of Republic Act No. 8423, otherwise known as the Traditional and Alternative Medicine Act of 1997 ("TAMA") states:

SECTION 2. Access to Biological and Genetic Resources Including Indigenous Knowledge Systems. – The Institute shall endeavor to effectively implement laws, executive issuances and ordinances governing access to the country’s biological and genetic resources. It shall assume the responsibilities of the Traditional Medicine Unit as a member of the Inter-Agency Committee on Biological and Genetic Resources under Executive Order No. 247, the Sub-Committee on Biodiversity of the Philippine Council for Sustainable Development, the National Committee on Biosafety of the Philippines and other developmental bodies and councils provided by law and executive issuances. In order to carry out this transfer, the Board shall make the appropriate representations to the Secretary of Health.

The Provisions of existing laws and regulations, particularly of existing laws and regulations, particularly Executive Order 247 and Republic Act 8371 or the Indigenous Peoples Rights Act must be complied with before access to biological and genetic resources can be made. Biodiversity prospecting activities that do not comply with existing laws and regulations on the subject as well as these rules shall be deemed an act of biopiracy. The Board shall take the appropriate steps, in collaboration with all branches of government, in order to penalize the perpetrators of these acts as well as to minimize and/or stop these activities.

SECTION 3. Documentation of Indigenous Knowledge Systems on Traditional and Alternative Health Care. – The Board shall endeavor to develop workable mechanisms, in accordance with the customary practices of the place, **for the identification and documentation of indigenous knowledge systems relevant to the utilization of biological and genetic resources that are applied in traditional and alternative health care practices of the community.**

SECTION 4. Intellectual Property Rights. – All products and by-products derived from Philippine medicinal plants using the resources and facilities of the Institute in their development shall be the property of the Institute and the Philippine Republic.

The Institute shall likewise endeavor to develop its intellectual property rights portfolio to maximize the benefits that can be derived from the various intellectual properties that it may secure from its research and development activities.

Assistance to Filipino inventors, scientists and entrepreneurs in the form of efforts in securing appropriate intellectual property rights and technology transfer agreements in the Philippines and abroad shall be provided by the Institute. Whenever appropriate and necessary, the Institute shall apply for intellectual property rights protection in accordance with applicable treaties and laws for any material, products and by-products derived from medicinal plants including

patents for the processes utilized in the manufacture of these natural products and by-products in behalf of the Philippine Government, Philippine Herbal Industry and other stakeholders.

The Institute shall endeavor to monitor and inventory Philippine natural health products that have been inappropriately applied for intellectual property rights protection in the Philippines and abroad without complying with applicable laws and regulations and shall make representations with the appropriate international institutions and agencies with assistance of other institutions and agencies of the Government of the Philippines, to cancel this rights or to renegotiate the terms and conditions thereof that are favorable to Philippine interests.

The application of existing forms of intellectual property rights on biological and genetic resources as well as indigenous knowledge systems shall be without prejudice to the application of whatever sui generis rights that may be provided by law to the appropriate local and indigenous communities. The Board or other appropriate governmental bodies shall also intervene, whenever it becomes necessary for the protection of the general welfare of the communities during the negotiations for benefit sharing.

If yes, please quote the corresponding text from the law or regulations and reply to the following question, if applicable:

a) Are these regulations found in patent law, general IP laws or in legislation implementing the Convention on Biological Diversity?

Answer: In legislation implementing the Convention on Biological Diversity.

b) What “triggers” the disclosure requirement, i.e. how close must the relationship of the invention to the biological/genetic resource be to require disclosure?

Answer: Even indirect connection to the biological/genetic resource requires disclosure.

c) Is it clear what the concept of “source” or “country of origin” or “country providing the resource”, and “based on genetic resource/traditional knowledge” or “derived from biological resource and associated traditional knowledge” means and what information must be included in the patent application?

Answer: Yes.

d) Is the disclosure requirement limited to biological/genetic resources or traditional knowledge of your country only or is it applicable also to biological/genetic resources or traditional knowledge obtained or obtainable from other countries and geographical areas?

Answer: Also from other countries.

e) Are there ways to complement, correct or amend the corresponding text in the patent application after filing?

Answer: Yes

f) Is disclosure of “prior informed consent” and/or agreements on “fair and equitable benefit-sharing” required?

Answer: Yes

g) Are human genetic resources treated differently or the same way as animal or plant genetic resources falling under the CBD?

Answer: No.

h) Is traditional knowledge properly defined, and is the source of traditional knowledge to be indicated only if it is connected to genetic/biological resources (e.g. falling under the CBD) or in general?

Answer: Yes.

i) Are sanctions foreseen for non-compliance (e.g. patent invalidation, revocation or lack of enforceability, patent transfer to the owner of the resource, fines, criminal sanctions etc.)?

Answer: Yes.

j) Does the law/regulation indicate that access to a genetic/biological resource would not mandate a disclosure in the patent application, if such access had occurred prior to a particular date, e.g. prior to the date of entry into force of the CBD?

Answer: No.

2) Please indicate your experience with the application of the legal requirement as listed under 1) when filing and prosecuting patent applications in your country.

Answer: None.

3) Please give statistical data on the number of applications mentioning source and/or country of origin of genetic resources and/or traditional knowledge, following the legal requirement as listed under 1) in your country. If such data are not available, please give an estimate of the number of such applications.

Answer:

Statistical Data – None (not available at the IPO)

Estimate number – 50-100 (samples – please see attached)

4. Please indicate whether administrative or judicial decisions on the application of the legal requirement as listed under 1) are available. If yes, please provide the text of such decisions.

Answer: No.

5. If there is no legal requirement of indicating the source and/or country of origin of genetic resources and/or traditional knowledge in patent applications for inventions based on such genetic resources or traditional knowledge in your country. (please see Answer to No. 1). Do you know of any project of law in your country dealing with the topic?

Answer: None.