KUO, W.H.J. and J.H. CHEN 2006 Drafting the Genetic Resource Act of Taiwan. Euro-Asian IP Forum II, The Limitation of Contemporary IP System in Knowledge Trading. Hsinchu, TAIWAN.

Drafting the Genetic Resource Act of Taiwan

Jau-Hwa CHEN[1] and Warren H.J. KUO[2]

[1] Professor, Department of Financial and Economic Laws, Fu-Jen Catholic University.

[2] Professor, Department of Agronomy, National Taiwan University.

I. Introduction
II. The drafting process: First year
III. Basic considerations and main points of the draft
A. Basic considerations
1. Following relevant international instruments
2. Genetic resources to be treated separately with traditional knowledge
3. Definition and scope of genetic resources
4. Focus on the access and benefit-sharing of genetic resources
5. Recognition of sovereign rights of states over their natural resource
6. Application and approve procedures are differentiated based on the nature of access
7. Basic principles for the approval of bio-prospecting
B. Main points of the draft
1. Legislation purpose
2. The scope of the Act
3. Application and approval of bio-prospecting
4. Post supervision and control
5. Export of genetic resources
6. Disclosure of origin in patent applications
7. The biodiversity fund
IV. Final remark

I. Introduction

From the nineteen sixties onward, more and more governmental institutions and biotech companies of developed countries put their effort on exploring genetic resources, mostly in developing or underdeveloped countries. They invest huge capitals to collect genetic resources for the screening of potential chemicals. These activities are often known as bio-prospecting. In fact, genetic resources may be utilized in all respects of human lives, especially in the sectors of agriculture and pharmaceutical. However, once the resources poor but technology advanced countries were able to make invention from

genetic materials they acquired form the south countries, frequently they would ensure their rights of the invention, or sometimes even on these genetic resources by intellectual property rights, which has been called “biopiracy”, a phrase coined by NGOs and southern countries. South-North conflict on genetic resources has been since a hot issue in various international fora.

Agricultural productions of Taiwan are very much indebted to foreign genetic resources. More than 95% of the plant species now cultivated were introduced to the island during the long history of human inhabitation. Cultivated staple crops such as rice, millets, taro and sweet potato; vegetables such as cabbage, pea and sweet pepper, fruit trees such as banana, mango and pineapple, cash crops such as sugar cane, tea and tobacco, ornamental crops such as chrysanthemum, roses and *Phalaenopsis* are all of foreign origin or at least bred with foreign cultigens or wild species. For example, Taiwan boosts 50% share of the international market in *Phalaenopsis* industry. However, only two native species occurs in Taiwan, which are also distributed in area of the Southeast Asia. While totally the *Phalaenopsis* genus has more than 60 species, many of which contribute to the famous breeding activities of this country.

On the other hand, although Taiwan occupies only 0.03% of terrestrial acreage on the earth, the islands host a great variety of life. We have more than 5000 native plant species (2.1% of the world sum), more than 29000 native animal species (3.4%), and more than 10000 native microbe species (8.6%). In above categories, percentage endemic species of fungi, birds, plants, reptiles and insects species are 2, 17, 25, 31 and 62.5% respectively. Some of these have been introduced to other countries for commercial production. For example, varieties of *Epinephelus awoara* (fish) and *Penaeus monodon* (shrimp) have been exported to and cultivated in Australia and Brazil respectively. Local varieties of millets, which were carried to Taiwan at least several thousand years ago by the indigenous peoples, had been collected in the National Seed storage Laboratory, USA. In 1970s, an American collected seedlings of *Rhododendron oldhamii* from Taipei. Several years later, a variety ‘Forth of July’ was selected from the offspring of the original seedlings. Crossing with ‘Forth of July’ a breeder was able to create 14 hybrids and US

plant patents were granted. *Nothapodytes nimmoniana* (synonym *N. foetida,*), a native plant of the Orchid Island, had been planted and raw materials exported to Kabushiki Kaisha Yakult Honsha, a Japanese pharmaceutical company, in where camptothecin were extracted and further processed into irinotecan hydrochloride, (CPT-11, Campto), which has been widely used in the world to cure colon cancer.

During last decade, a Welsh nurseryman had been to Taiwan several times hunting plant of ornamental potential in the mountain area, and collecting more than 2000 accessions of samples. Many plants have been put on the sale list. Among them at least three varieties of *Clematis*, *Cardiandra*, and *Tricyrtis* have been selected from the accessions brought back to Wales.

Apparently the status of Taiwan in terms of genetic resources is quite unusually, if not unique. One the one hand, we have strong breeding activities in agriculture, both public and private sectors. Vast number of foreign genetic materials have been and being used in the breeding programmes. On the other hand, bioprospecting by persons of other countries have been a long history. Unfortunately, until now there are still no proper regulations to manage the acquisition of genetic resources.

II. The drafting process: First year

While Taiwan is not one of the parties of the Convention on Biological Diversity, scholars and NGO members had attended various CBD meetings since 1992. Nevertheless most of the attendants are biologists, and their reports back to the country were concentrated on the scientific issues of biological conservation. After 1996, when specialists of environmental law began to notice the social and legal issues underlining CBD, voices to draft regulations on genetic resources emerged. In 1998 the Council of Agriculture announced that a law concerning the management of genetic resources would be proposed. However the progress is slow. Not until the end of year 2004 had we been mandated to draft the Genetic Resource Act.

Immediately after the commission, a drafting team was recruited. The team is composed of four biologists and four law professors. The biologists are asked to investigate state of the art the bioprospecting activities in Taiwan by

overseas natural person and/or legal person. The Law team was to make comparative studies on the regulations of selected countries and of international instruments.

After intensive studies, framework of the Genetic Resources Act of Taiwan was settled on the 1st July at the 7th meeting of the Law team. The first preliminary draft was finished 45 days later. Together with the preliminary draft, a booklet "Access and Benefit-sharing of Genetic Resources" was prepared and distributed to various stakeholders, such as taxonomists, pharmaceutical companies, biomaterial exporters, NGOs, as well as government officials, professors and lawmakers. The preliminary draft is to be subjected to public criticism by several round table discussions.

III. Basic considerations and main points of the draft

A. Basic considerations

At the beginning of setting the framework of the Act, we identified several aspects concerning the basic principles of the draft.

1. Following relevant international instruments

Presently, CBD and Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization are the main international bodies working on the issue of genetic resources. Even though Taiwan is the party of neither organization, we still keep in mind the conventions adhere to these two organizations when drafting the act.

CBD was adopted at United Nations Conference on Environment and Development, called for short "UNCED" on June 1992 and entered into force in December 29th, 1993. The objectives of this Convention are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including appropriate access to genetic resources and appropriate transfer of relevant technologies (Article1).

In Article 15 (Access to Genetic Resources), the Convention recognizes the right of each state the sovereignty over their natural resources, and national

governments can set rules of access to their genetic resources by national legislation. Principle of prior informed consent, access and benefit sharing are also rested in this clause. How to implement these principles remained to be proposed until the non-legal binding Bonn Guideline was adopted.

For the purpose of executing the relevant provisions of access and benefit-sharing of genetic resources in CBD, Secretariat of the Convention held three times of intergovernmental meeting discussing how to draft the international principle of access and sharing benefits of genetic resources, and eventually prepared the draft of “Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization“ at the work group meeting on October, 2001. The Guidelines were approved by the Conference of the Parties to the Convention at its sixth meeting, held in April 2002. Each parties of the CBD are voluntarily but not obligatory to follow or execute the provisions of the Guidelines until the Guidelines were upgraded to be protocols so that they are legally binding. However, due to their detailed provisions, it was an important reference for our draft.

International Treaty on Plant Genetic Resources for Food and Agriculture was signed at Food and Agriculture Organization of the United Nations on November 2001 and entered into force on June 2004. Fearing that the implementation of CBD and Bonn Guideline might hinder breeding efforts of agriculture crops and eventually hamper the security of food and agriculture of the whole world, the main point of the Treaty is to create a multilateral system, within which the access of some 60 species of agricultural crops are to be facilitated. Parties of the Treaty are entitled to acquisit those germplasm within the system without applying to, reviewing by and signing contracts with provider countries. This Treaty also specified that the interests of the genetic resources arising out of their use should be fairly and equitably shared accordance with system. Intellectual property rights arising from the germplasm and those derived from the germplasm are also considered.

In the draft, we are inclined not to treat separately the plant species which were within the multiple system of the International Treaty on Plant Genetic Resources for Food and Agriculture. The reason is that none of the crops

within the multiple system were originated from Taiwan, and virtually all their local varieties developed by farmers of past generations have been stored in the National Plant Genetic Resource Center. The NPGRC may take some measures to comply with the Treaty though.

2. Genetic resources to be treated separately with traditional knowledge

Although we recognized that indigenous peoples have developed tremendous knowledge concerning the use of biota in their surroundings, and some countries in their legislation put together both issues, it is unpractical to do so in the Act of Taiwan. In the 5th February 2005, the Basic Law of the Indigenous Peoples started to enforce. Among the clauses, Article 13 states clearly that the government should protect by acts the knowledge concerning conservation of biodiversity and intellectual creations of the indigenous peoples. In Article 22, academic research, ecological conservation, land exploration, and resources utilization should be subjected to prior informed consent of and/or participation of the indigenous peoples. Mechanism of sharing profits that are arising from the commercial utilization should be established. To avoid introducing a “diarchy” system, we propose that the competent authority of genetic resources to be the due office of the Council of Agriculture, and that of traditional knowledge to be the Council of Indigenous Peoples. Interface of both Acts should be considered carefully. Fortunately the same team has been asked later to draft an act concerning the protection of the traditional knowledge of the indigenous peoples. That makes the task easier.

3. Definition and scope of genetic resources

According to Article 2 of Convention of Biological Diversity, "Genetic resources" means genetic material of actual or potential value and "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity. It is clear that genetic resources include any material of plant, animal, microbial or other origin that contain functional units of heredity of actual or potential value, exclude those belong to human.

We define genetic resources as biological materials that contain genetic units

by which the biological materials can reproduce by themselves or with the help of peoples. With this definition we exclude dried herbarium specimen that contain no viable seeds from control under this Act. Criticism concerning this point came from round table discussion. It is claimed that DNA embodied in dead tissues can be extracted, sequence determined and the potential application explored. Another concern is whether exporting biomaterial aimed for the use of the biological material per se (not for the purpose reproduction), such as material medical and living plants for flower or plant arrangement, should be under control by the Act. We propose that these are subjected to traditional use of biological materials, and thus were exempted from control under this Act together with human genetic resources. These exemptions were also said to be a let-out. We acknowledged the possibility of let-out in both cases; however, leakage-prove legislation will not only cause inconvenient procedures in exporting trade, but also practically impossible, due to the fact that tiny amount of sample is enough for scientists to extract the DNA contents.

If we admit that the probability of successfully bioprospecting in terms of profit making is actually very low, then one of the solutions to the above-mentioned dilemma is to put more weight on the control of bioprospecting activities, rather than on the materials of genetic resources. In this context, seeds or young plants of cultivated plants in international trade for the purpose of planting should be excluded from the scope of the Act. The intellectual property right of new varieties of cultivated plants should be protected under Plant Variety and Plant Seed Act. Export of living wild organisms should be under control only if they are native to Taiwan. Living native plants for flower or plant arrangement should be checked before exporting to ensure that the samples are not gained from bioprospecting activities. The exchange of herbarium specimen can be allowed only if the material transfer arrangements have been made.

4. Focus on the access and benefit-sharing of genetic resources

The objectives of CBD are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. However, the

scope of conservation of biological diversity and the sustainable use is quite broad; conservation, access of genetic resources and the role of indigenous peoples in conservation are only parts of it. Legal framework is set to deal with the access and benefit–sharing of genetic resources only, and leave alone the complete regime of biological diversity conservation. The reason is that there are already several acts dealing with different aspects of biological diversity, such as Wildlife Conservation Act, The Forestry Act, National Park Law, Cultural Heritage Preservation Act, and Basic Act of Indigenous Peoples *et al.* To draft a single biodiversity act will meet a lot of difficulties. For example, it is related to the change of administrative organizations, economic development and power and responsibility of the regional planning and concurrence in laws, to name a few. The above problems make it impossible within the time constrain to devise a new biodiversity act. Thus, this draft focuses on the issues of access and benefit sharing of genetic resources.

5. Recognition of sovereign rights of states over their natural resource

Both CBD and International Treaty on Plant Genetic Resources for Food and Agriculture recognized sovereign right of state on genetic resources. Article 3 of CBD provides that States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not damage the environment of other States or of areas beyond the limits of national jurisdiction. International Treaty on Plant Genetic Resources for Food and Agriculture also has similar provision in Article 10. Following above provisions, our draft states the purpose from the very beginning that the sovereign right of genetic resources belongs to the State. Based on this provision, the state shall be entitled to consider whether it shall authorize others to access genetic resources, judged by state's interests comprehensively. For example, it shall take into account the effects on local and margin environment, society, traditional culture, the livelihood custom of inhabitant as well as national policies, such as defense, economy and environment protection. The State also has the right to make final decision and to coordinate benefit sharing. The Bonn Guidelines provides that each

Party shall designate one national focal point for informing applicants for procedures of applying access to genetic resources, including where competent national authority and stakeholders are, how to acquire prior informed consent and mutually agreed terms. Our draft does not designate the nature and the composition of the national focal point. We meant to leave it for the competent authority to reschedule its organization. The competent authority shall bear the responsibility for the execution and supervising of this Act.

6. Application and approve procedures are differentiated based on the nature of access

The execution of all bioprospecting activities needs to be done only after approval. However, it is not proper to create excessive disturbance to academic researches during the application and approving process, which will obstruct the research process, and in turn may deter the biological conservation *per se*. Thus, the application and approving procedure for academic research should be different from that of commercial bioprospecting. For the pure academic researches, the procedure shall be set looser, while the procedure for the commercial purpose should be much stricter. However, to avoid unintentional or intentional leaks that resulted from commercial utilization in the name of academic research, the draft should provide mechanism to ensure that the genetic materials acquired from academic researches can only be used for academic research. In case that the genetic materials or the derived materials or technologies are to be commercialized, the applicants are obligatory to resume the application and approval process in accordance with the stricter procedure.

7. Basic principles for the approval of bio-prospecting

As to Access to Genetic Resources, Article 15 of CBD recognizes the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation (Section 1, Article 15). Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party (Section 5, Article 15). Moreover, it also provides that each Contracting Party shall

take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development, as well as the benefits arising from the commercial and other utilization of genetic resources with the contracting party providing such resources. Such sharing shall be upon mutually agreed terms (Section 7, Article 15).

The Bonn Guidelines provides detailed clauses suggesting how to design the procedures managing the access of genetic resources and benefit-sharing as stipulated in CBD.

(1) prior informed consent:

The Guidelines propose that national legislations should be of legal certainty and clarity; they should be able to help accessing genetic resources at minimum cost; the restriction on access to genetic resources should be transparent and based on legal grounds. The competent authority shall grant the prior informed consent and this consent may be required from different levels of Government. The applicants shall provide various information, such as the type and quantity of genetic resources to be collected, starting date and duration of the activity, geographical prospecting area, how to evaluate the impacts that access activities might bring on biodiversity. The applicants also need to supply accurate information regarding intended use (e.g.: taxonomy, collection, research, commercialization), possible third party involvement, types of benefits coming from obtaining access to the resource and benefit-sharing arrangements. A national registration system could be used to record the issuance of all permits or licenses.

(2) Mutually agreed terms

The landholders shall consent a prospecting application only when both the landholders and the explorers reach a mutually agreement. Basic requirements for mutually agreed terms are legal certainty and clarity, minimization of transaction cost and negotiation time, obligations of resource providers and users. Different resources and uses shall develop different contractual arrangements. Considering that many landholders may not have

enough capability to negotiate with the explorers, it is essential that the competent authority should assist them in some way.

(3) Benefit-Sharing:

Mutually agreed terms could cover the conditions, obligations, procedures, types, timing, distribution and mechanisms of benefits to be shared. Near-term, medium-term and long-term benefits should be considered, including up-front payments, milestone payments and royalties. Benefits should be shared fairly and equitably with the resource management, scientific and/or commercial process. The latter may include academic, governmental, or non-governmental institutions, as well as indigenous and local communities. Benefit sharing shall be divided into monetary and non-monetary benefits. Monetary benefits may include fees per sample, up-front payments, milestone payments, salaries, research funding, special fees to trust funds supporting conservation and sustainable use of biodiversity, license fees and joint ownership of intellectual property rights.

Non-monetary benefits may include sharing of the results of research and development, technology transfer, participation in product development, collaboration, cooperation and contribution in education and training, admittance to *ex situ* facilities of genetic resources and to databases, and contributions to the local economy.

B. Main points of the draft

The main points of the draft of the “Genetic Resource Act” are as follows:

1. Legislation purpose

The purpose of this act is to promote the conservation and the utilization of genetic resources that embodied in the diversified biota, and to ensure fair and equitable sharing of the benefits that arose from the development and utilization of the genetic resources. The draft did not depict “Conservation” *per se*; instead, “promote” the conservation was used. The reason is that we already have had several laws concerning conservation, such as National Park Act, Cultural Asset Preservation Act, Wild Animal Conservation Act, and Forest Act. Harmonization of the Genetic Resources Act with these acts will

not be easy, if the Genetic Resources Act shall cover all aspects of conservation. Nevertheless, where the Genetic Resources Act is not applicable, those above laws shall apply.

2. The scope of the Act

Since we adopted the idea that the state owns the sovereign right over genetic resources, it is apparent that prospecting activities of foreign natural person and/or legal person should follow the requirements set in this Act. That is not to say that native person and/or legal person can be exempted from the regulation. In the era of global economy, it is meaningless to control the prospecting activities of foreigner alone. However, according to Article 19 of Basic Act of Indigenous People of Taiwan, indigenous People may collect plants and fungus on non-commercial purposes. Moreover, In Article 10c of CBD, each country should protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements; and Article 16 of Bonn Guidelines also emphasizes that the commercialization and any other use of genetic resources should not prevent traditional use of genetic resources. Thus in our draft, we exclude the traditional use of biological material from the regulation.

Besides the traditional use of the biological materials, human genetic resources are also excluded, according to Article 9 of Bonn Guidelines and Article 4 of Andeans No. 391 decision.

3. Application and approval of bio-prospecting

According to the draft, the procedures of applications and approval of bio-prospecting case are different based on the different nature of access, i.e., academic research or commercial exploitation. The bio-prospecting purely for the purpose of academic research, not for commercial exploitation, is named “the first class bio-prospecting” in the Act. On the contrary, those prospecting activities from which the genetic resources thus acquired are intended for commercial utilization immediately or may be exploited for commercial utilization in the future are named “the second class bio-prospecting”.

(1) The first class bio-prospecting

For the first class bio-prospecting, the application and approval procedure is quite simple (Fig. 1). On receiving application the competent authority should inform the landholder and ask for their consent. Under the consent of the landholder, understanding that no benefit sharing agreement to be discussed and made, it leaves the competent authority to examine the case, and to make the decision whether or not the acquisition request is permitted. The competent authority shall make the decision by criteria such as public interest and environmental impact, based on the contents of the documents delivered by the applicants. The documents shall include: 1. The purpose, the area, the duration, and the practice of prospecting; 2. The species and their quantity to be collected; 3. The anticipated results of research; and 4. The anticipated intention of transferring the germplasm thus acquired and/or the research result, as well as the material transfers agreement.

(2) The second class bio-prospecting

On the contrary, the application and approval procedure for the “second class bio-prospecting” (Fig. 2) is much stricter than that of the first class, in terms of prior informed consent and benefits sharing.

Besides the same documents as in the first class application, the applicants of the second class shall provide commercial use plan, illustrating the possibility of commercial use and expected economic outcomes. The competent authority shall examine and make the decision by criteria such as public interest and environmental impact, based on the contents of the documents delivered by the applicants. In this phase, the competent authority shall decide whether or not the acquisition request be permitted, without informing the landholder, although experts may be consulted during the examine process.

After the application case was accepted by the initial examination, the competent authority should then inform the landholder of the area to be prospected. The competent authority then invites the representatives of the landholder and the applicant to join a trilateral meeting to discuss the agreement concerning bioprospecting activities, material transfer, and benefit

sharing.

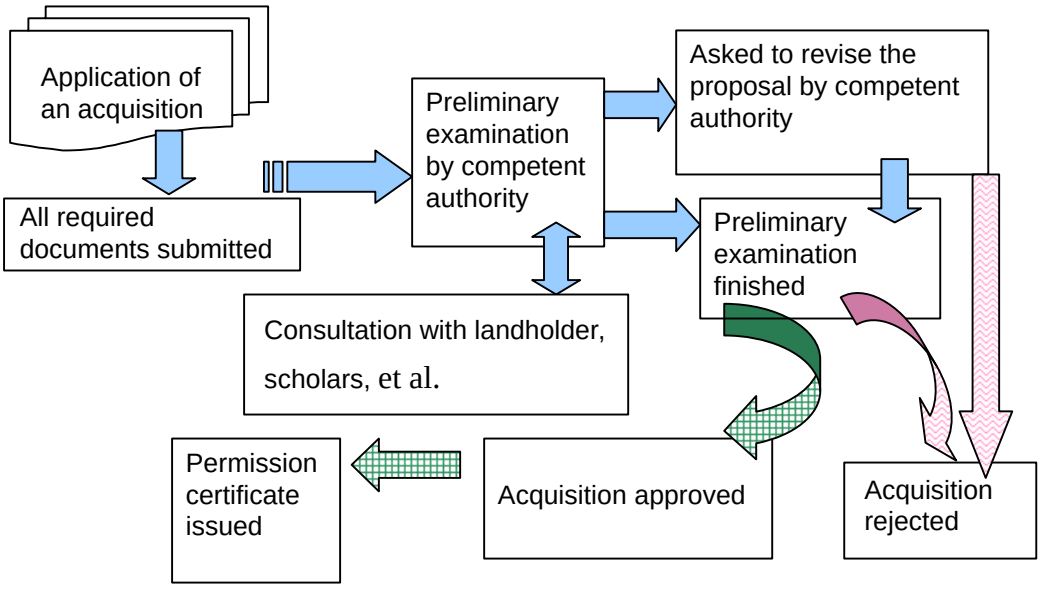

Fig. 1, Procedure of application and approval for the first class acquisition. (e.g. taxonomic exploitation)

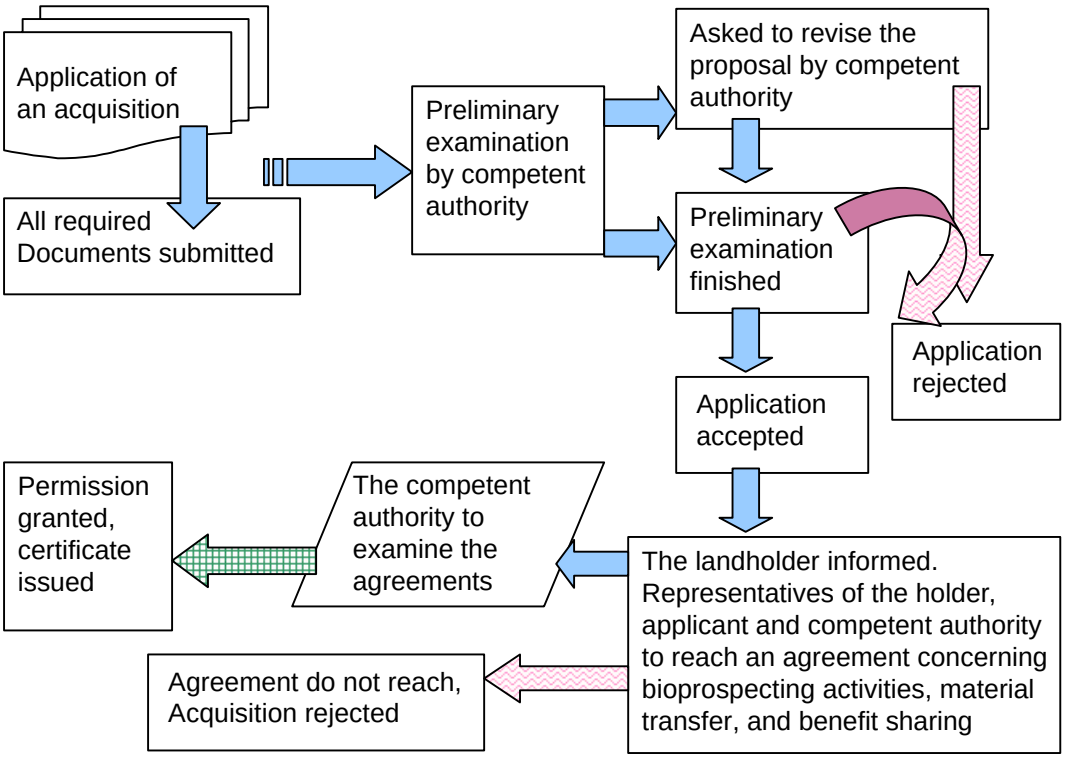

Fig. 2, Procedure of application and approval of the second class acquisition. (e.g. commercial

exploitation)

The competent authority may also invite the scholars and experts in relevant fields to present at the negotiation table. The landholder shall designate the representatives to attend the negotiation before the negotiation begins. During the negotiation, the applicants shall elaborate on the prospecting proposal. Afterwards, the interested parties together shall reach an agreement on the terms of fair and equitable benefit-sharing. The detail of the possible arrangements for benefit-sharing is not laid in the draft clause. However, these detail possibilities will be announced in other occasions, such as regulations or executing orders published by the competent authority, and extension booklets. The arrangement will follow those of the Appendix II of the Bonn Guideline. Benefit-sharing may pay in monetary or non-monetary ways. The monetary payments may adopt by up-front payments or milestone payments.

(3) Reaching an agreement:

After receiving the applications case of the first class prospecting, the competent authority may, in the condition that the informed landholders agree the academic prospecting, refuse or approve the application case. After approval, the applicant shall get a certificate and start the exploration, follow the proposal that pass the examination of the competent authority.

For the second class prospecting, mutually negotiation should be started only after that the competent authority has accepted the application case. Upon the completion of the negotiation, the competent authority is to examine the agreements in detail. The competent authority shall consider the following factors when making refusal or approval: a. The impacts of bio-prospecting activities on environments, society, traditional culture and the livelihood customs of inhabitants around the prospecting area; b. The impacts of bio-prospecting activities on national policies, such as national defense, economy, intellectual property rights and environmental protections around the area of prospecting; c. The opinions of stakeholders on the prospecting activities as well as the benefit-sharing arrangement; d. Whether the application case had violated other Acts or not. If the case is approved, the applicant shall get a certificate and start the exploration.

4. Post supervision and control

To ensure that the applicants execute the exploration is strictly following the proposal and the agreement that have been approved, the draft proposes that the applicants shall submit the reports of exploring activities to the competent authority from time to time. The reports should contain a. The progress of the bio-prospecting; b. Biological materials collected and the conditions of their transportation; c. Any information that is associated with the collected materials.

Moreover, the draft states that the applicants must notify the competent authority and the landholder should any commercial products have been derived from the acquired genetic materials. If after study the genetic resources acquired from the first class bio-prospecting activities are believed to be of commercial value, the applicants should proceed with the whole procedure of application and approval of the second class; any commercial activities concerning said genetic materials will be seen as offensive to the Act if not been approved by the competent authority.

Although tracing the outcome of the acquired genetic materials may be extremely difficult, especially after they were carried abroad, we proposed in our draft that the applicants should take the responsibility to ensure that any constraint by the Act on that acquired materials should be sent to the third party if the materials are to be transferred to that party. We acknowledge that it is only a passivism at best; any deliberately takeover of the material without the consent of the applicants will invalid the control of the Act.

5. Export of genetic resources

The acquired genetic resources in the bio-prospecting activities of both classes may be allowed to export, except those already have been forbidden to export by the competent authority or by other regulations. To acquire export permits the applicants shall deposit a copy of each live sample to due germplasm bank, along with the Material Transfer Agreement.

The exports of any genetic material that is not acquired through legal activity,

which means bioprospecting approved by this Act, deem to be offensive to the Act. In order not to deter academic research, the dead specimens are free to export according to the draft. In the round table meeting, this clause is challenged. It is claimed that the clause will allow free access of the domestic genetic resources by foreign institution through DNA extraction technique. Providing proper Material Transfer Agreement in the exchange or loaning process of dead specimens seems to a possible compromise.

6. Disclosure of origin in patent applications

The origins of the genetic resources in a patent application should be or should not be disclosed has been a hot issue in many international fora. While the Unites State censures the notion, those countries such as the African Group strongly suggest that, and claim that failing of disclosure shall invalid the patent even after the granting. European Union stands in the middle way. Although encouraging the disclosure, they do not agree with the idea that the disclosure be one of the essential requirements for granting a patent.

Regarding whether the disclosure the origins of genetic resource shall be one of the patent requirement, we do not yet reach a consensus in Taiwan. Not to say that it is improper to put the clause of patent requirements in this Act. However, it is up to the IP competent authority to consult the competent authority of the Act on an IP application case whether or not there is a possibility of using genetic materials of Taiwan origin.

However the competent authority of genetic resources has the right and the obligation to put the requirement of disclosure commitment as one of the criteria approving the application case of bio-prospecting. Thus, the draft of this Act states that the applicants shall submit the permits for exploring genetic resources in Taiwan to the competent authority of IP, and to describe the origins of genetic resources they used for the invention when applying for patent or plant variety rights if the genetic resources were acquired in accordance with the Act. Any one who fails to disclose the facts that their invention is related to the use of genetic resources, which are acquired from Taiwan, deem to infringe the Act of Genetic Resources, but not yet the Patent Act of Taiwan.

7. The biodiversity fund

According to the draft, both the monetary and non-monetary benefits should be shared with the state and the landholder in a fair and equitable manner. How many percentages of the benefits thus collected from one case should be allocated to the landholder remains to be solved.

The monetary benefits shall be collected by the competent authority, which will establish a biodiversity fund the function of which is to allocate all possible capitals in favour of biodiversity, for example, to establish the conservation institutions, as well as to maintain and promote the research and exploitation of related genetic resources, and training of human resources related to the preservation and utilization of genetic resources.

IV. Final remark

Gene technology has brought the world new era of bio-industry. The power and speed of discovering new chemicals with a high degree of commercial potential from tiny pieces of bio-tissue have appeared in an unprecedented way. However, the new technology may lead some changes in, but could not ever diminish ordinary life. An idea Genetic Resources Act shall be the one that ensures effective control over the genetic resources within the territory of the country, meanwhile exerts least inconvenience on ordinary life and common practices such as academic research, education, and trade. Apparently our draft is still far from that goal. Any critics and suggestions are most helpful.