

Genetic Resources Protection and The Intellectual Property System — Practices in China

YANG Hongju

Legal Affairs Department
State Intellectual Property Office

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- Genetic resources (GR), traditional knowledge (TK) and folklore (FL), as sources of and bases for innovations, are invaluable assets to countries worldwide and shall be cherished and protected. Accordingly the people who hold, preserve and transmit them shall also be duly respected, and their reasonable claims shall be valued and considered.

INTRODUCTION

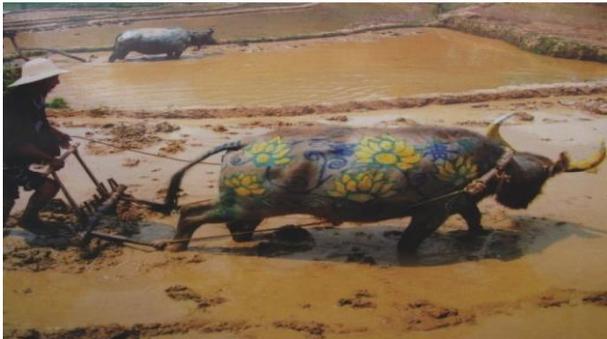


Overview of Genetic Resources Protection in China

- China, a country with vast territory and rich biodiversity, boasts of multitudinous unique genetic resources.
- The Chinese government attaches great importance to the protection and management of biological genetic resources, and a number of government agencies are involved for that purpose, which, according to the division of their respective functions, include the ministries of environment, agriculture, forestry and marine protection.
- *National Planning Outline for the Conservation and Utilization of Biospecies Resources and China National Biodiversity Conservation Strategy and Action Plan (2011–2030)* were successively released.
- China's basic principles for the biodiversity conservation strategy are **“Priority on conservation, sustainability in utilization, engagement by the public and sharing of benefits.”**

Overview of Genetic Resources Protection in China

- With respect to legislations, in addition to the requirements of constitutional principles, China has promulgated relevant laws and regulations for the protection of crops, wildlife, wild plants, domesticated animals and plant varieties.
- The *Animal Husbandry Law* sets out the principles for the acquisition and utilization of related genetic resources.



Overview of Genetic Resources Protection in China

- In 2008, China has explicitly put forward the following policy objectives in its *Outline of the National Intellectual Property Strategy*:
 - Strengthen the protection, development and utilization systems for genetic resources to prevent loss and inappropriate use of them. Balance interests between the need to protect genetic resources and the need to develop and utilize them, and to develop a reasonable mechanism for genetic resource access and benefit sharing. We must guarantee the right of prior-informed consent enjoyed by suppliers of genetic resources.

- Intellectual property rights and protection of genetic resources
 - To make full use of the intellectual property (IP) system to grant protection to innovation outcomes based on GRs and associated TK (patent, trademark, copyright, design, trade secret, geographical indication, etc.);
 - To improve the IP system by applying higher criteria for granting rights, building up examination capacity and establishing defensive protection mechanisms to prevent undue granting of IP rights (criteria for inventive step; databases);
 - To reform the IP system to make it effectively connected to and mutually supportive of the protection mechanisms for GRs and TK (disclosure of the origin of GRs)

- ***The Patent Law***

- Article 5.2: No patent right shall be granted for any invention-creation where acquisition or utilization of the genetic resources, on which the development of the invention-creation relies, is not consistent with the provisions of the laws and administrative regulations.
- Article 26.5: Where an invention-creation is developed relying on the genetic resources, the applicant shall indicate, in the application documents, the direct and original source of such genetic resources. Where the applicant fails to indicate the original source, he or it shall state the reasons thereof.

- **Specific provisions in the *Implementing Regulations of the Patent Law* and the *Guidelines for Patent Examination***
 - “Genetic resources” mean the material obtained from such as human body, animal, plant, or microorganism which contains functional units of heredity and is of actual or potential value.
 - The “invention-creation is developed relying on the genetic resources referred to in *the Patent Law*” means that the invention-creation is developed relying on the use of the heredity function of the genetic resources.

- **Specific provisions in the *Implementing Regulations of the Patent Law* and the *Guidelines for Patent Examination***
 - “Heredity function” refers to the ability of organism to pass on traits or characteristics from an ancestor to a descendent through reproduction, or allow the entire organism to be reproduced. Functional unit of heredity refers to a gene, or a DNA or RNA fragment having heredity function of an organism.
 - “Material obtained from such as human body, animal, plant or microorganism which contains functional units of heredity” refers to carrier of functional units of heredity, which includes not only a whole organism, but also a part of it, such as organ, tissue, blood, body fluid, cell, genome, gene, DNA or RNA fragment, etc.

- **Specific provisions in the *Implementing Regulations of the Patent Law* and the *Guidelines for Patent Examination***
 - With regard to an invention-creation, “using the heredity function of the genetic resources” refers to, for example, isolating, analyzing and/or processing the functional units of heredity to develop the invention-creation and to realize the value of the genetic resources.
 - “Direct source of the genetic resources” means the direct channel to obtain the genetic resources. When indicating the direct source of the genetic resources, the applicant shall provide such information as the time, place, means of provider, etc., on acquisition of the genetic resources.

- **Specific provisions in the *Implementing Regulations of the Patent Law* and the *Guidelines for Patent Examination***
 - “Original source of the genetic resources” means the place in the *in-situ* conditions where the organism to which the genetic resources belong is collected. Where the organism naturally occurs, the *in-situ* conditions refer to the natural habitats where this organism grows. Where the organism is a cultivated or domesticated species, the *in-situ* conditions refer to the surroundings where this organism has developed its distinctive traits or characteristics. When indicating the original source of the genetic resources, the applicant shall provide such information as the time, place and collector, etc., on the collection of the organism to which the genetic resources belong.

- **Specific provisions in the *Implementing Regulations of the Patent Law* and the *Guidelines for Patent Examination***
 - Where an application for patent is filed for an invention-creation the development of which relies on the use of genetic resources, the applicant shall state that fact in the request, and fill in the forms provided by the patent administration department under the State Council. The contents in the registration form do not belong to the disclosure contained in the initial description and claims. Therefore, it can neither be used as the basis to judge whether the description has sufficiently disclosed the claimed invention, nor as the basis to amend the description and claims.

The disclosure form

遗传资源来源披露登记表修改样页

请按照“注意事项”正确填写本表各栏		第②和第④栏未确定的由国家知识产权局填写	
①发明名称		②申请号	
③申请人		④申请日	
⑤遗传资源名称			
⑥遗传资源的直接获取途径 I 遗传资源取自或属于： <input type="checkbox"/> 动物 <input type="checkbox"/> 植物 <input type="checkbox"/> 微生物 <input type="checkbox"/> 人 II 取自或属于的生物体或其部分的获取方式： <input type="checkbox"/> 购买 <input type="checkbox"/> 赠送或交换 <input type="checkbox"/> 保藏机构 <input type="checkbox"/> 种子库（种质库） <input type="checkbox"/> 基因文库 <input type="checkbox"/> 采集 <input type="checkbox"/> 其他			
⑦直接来源 （非采集方式填写）	⑧获取时间	____年____月	
	⑨提供者名称 （姓名）		
	⑩提供者所处 国家或地区		
⑪原始来源	⑪提供者联系 方式		
	⑫采集者名称 （姓名）		
	⑬采集者联系 方式		
	⑭获取时间	____年____月	
⑮无法说明遗传资源原始来源的理由	⑯获取地点 （国家、省 （市））		

**Name
of GR**

**Direct acquisition
approach of GR**

**Direct
source**

**Original
source**

**State the reason for the
failure of disclosure of
original source**

CONCLUSIONS

- To regulate the access to and utilization of GRs to realize benefit-sharing is not contradictory to the promotion of scientific research and innovation.
- The requirement for disclosing the origin of GRs does not inflict unbearable burdens on applicants and examiners, but rather facilitate the connection of patent system to relevant protection mechanisms for GRs.
- It is desirable to explore and establish, as soon as possible, a set of effective international rules to enhance the protection of GRs and to expand the social functions of the IP system so that the IP system could play a stronger role in promoting social developments.



Thank you!