



Controversial ABS Issues in China

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1, Existing laws on biodiversity in China

- **Existing laws and regulations:**
 - The Forestry Law(1984, latest revision 1998), the Grassland Law(1985, latest revision 2002), the Fishery Law(1986, latest revision 2004), the Wild Animal Protection Law(1988), the Environmental Protection Law(1989), the Seeds Law (2000, latest revision 2004), the Stock-breeding Law(2005), the Regulation on Nature Reserve(1994) , the Regulation on the Protection of Wild Plants(1997), the Regulation on the Protection of Wild Medicinal Resources(1987), the Regulation on the Import and Export of Endangered Wild Fauna and Flora(2006).....
- **The ownership of biological resources :**
 - Generally the State owns wild biological resources.
 - As exceptions, local communities , natural or legal person can own.
 - Subject to relevant laws, biological resources can be traded between the state and private sectors.

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1, Existing laws in China (cont'd)

- **Benefit-sharing rules in existing laws:**
 - Mainly focus on the ownership and conservation issues.
 - No benefit-sharing requirement in most laws.
 - Two exceptions:
 - The Stock-breeding Law (Art.16) : When exporting genetic materials on **Protected List**, **benefit-sharing arrangement** and **Governmental Approval** needed. [“Animal Husbandry Law”]
 - The Regulation on Human Genetic Materials (Art.19) : **Prior Informed Consent** of donators and **Governmental Approval** needed; Invention derived should be **co-owned** by the Chinese researchers and international partners.

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2, Disclosure Rules in the Patent Law

- ABS and Patent Law
 - The Patent Law of 2008
 - Implementing Rules for the Patent Law (2010)
 - Guidelines for Patent Examination (2010)
- **Art. 5 para.2 of the Patent Law of 2008:**
 - No patent right shall be granted for an invention-creation that is based on (developed relying on) the genetic resources which are obtained or utilized in the way violating relevant laws or administrative regulations.
- **Art. 26 para.5 of the Patent Law of 2008:**
 - For an invention based on genetic resources, the applicant shall state the **direct source** and the **original source** of the genetic resources in the application documents. If the applicant is not able to state the original source, **it or he shall state the reasons**.

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2, Disclosure Rules in the Patent Law

- Scope of Art.5 para.2:
 - “Genetic resources”:
 - Implementing Rules for the Patent Law of 2010, Art. 26: Genetic resource referred to in the Patent Law means human, animal, plant or microorganism-derived material etc. containing functional units of heredity and having actual or potential value.
 - “Relying on”:
 - The invention-creation made relying on the genetic resource referred to in the Patent Law means an invention-creation that is accomplished by using (developed relying on) the functional units of heredity of the genetic resource.
 - “Laws or administrative regulations” :

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2, Disclosure Rules in the Patent Law

- **“Laws or administrative regulations” :**
 - Only laws enacted by NPC and its Standing Committee, or regulations by State Council .
 - Laws with specific ABS rules:
 - [The Stock-breeding Law of 2005, Art.16](#)
 - Low-level regulations, relevant but not applicable:
 - [The Interim Measures on Human Genetic Resources \(IMHGR\) of 1998](#), jointly issued by the Ministry of Public Health and the Ministry of Science and Technology.
 - Other laws and regulations without ABS rules:
 - [See “existing laws regulations”](#)
 - Most important regulation in the future:
 - Regulations on Biological Genetic Resources.

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2, Disclosure Rules in the Patent Law

- ***The Stock-breeding Law of 2005, Art.16***
 - Where any livestock or poultry genetic resource included in the protection list is to be exported from China or is to be investigated and utilized within China in cooperation with any foreign institution or individual, the applicant shall file an application with the stockbreeding and veterinary administrative department of the provincial people’s government and shall simultaneously put forward a plan on sharing the benefits with the state.
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 - Before a newly found livestock or poultry genetic resource is appraised by the National Commission for Livestock and Poultry Genetic Resources, it shall not be exported from China nor be researched and utilized within China in cooperation with any foreign institution or individual.

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2, Disclosure Rules in the Patent Law

- *The Interim Measures on Human Genetic Resources (IMHGR) of 1998,*
 - Article 4 :
 - The State adopts a reporting and registration system on important pedigrees and genetic resources in specified regions. Any institution or individual who discovers or holds important pedigrees and genetic resources in the specified regions shall immediately report to the relevant departments. No institution or individual may sample, collect, trade, export human genetic resources or take them outside the territory of the People's Republic of China, or provide them to other countries in any form without permission.
 - Article 11 para.1:
 - Where human genetic resources in China are involved in any international collaborative project, the Chinese collaborating party shall be responsible for going through the due formalities of application for approval.

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2, Disclosure Rules in the Patent Law

- *The Interim Measures on Human Genetic Resources (IMHGR) of 1998*
 - **Art.19 para.1 :**
 - Patent shall be jointly applied by both parties and the consequent patent right shall be owned by both parties if an achievement resulted from the collaboration is patentable. ...
 - **Article 12 :**
 - An application form shall be filled in and the following documents be included in going through the applying and approving formalities of an international collaborative project involving human genetic resources of China:
 - (1)Informed consent form of the donor of the human genetic materials and/or his (her) legal representatives; [CuiNotes: No requirement for benefit-sharing with the donator]
 - (2) Draft contract; and
 - (3)Other documents required by the examining and approving departments.

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2, Disclosure Rules in Patent Law

- **Art. 26 para.5 of the Patent Law of 2008:**
 - For an invention based on genetic resources, the applicant shall state the **direct source** and the **original source** of the genetic resources in the application documents. If the applicant is not able to state the original source, **it or he shall state the reasons**.
 - **Direct source:** where the resources are obtained by the applicant
 - **Original Source:** where the resources are collected in situ.
 - **Legal consequence for violating Art.26 para.5:**
 - *Implementing Regulation Art. 44* (preliminary examination), Art.52 (substantive examination): Application rejected.
 - Once granted, cannot be invalidated for failing to disclose
 - **Patent Applications Affected :**
 - Very limited, about 1000-2000 applications per year?
 - Only applications involved “genes , cDNAs and their fragments”

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2, Disclosure Rules in Patent Law

- **Challenges:**
 - To what extent would a violation against Art.5 para.2 lead to invalidation of a patent?
 - **Agency problem:**
 - Biological resources are usually collected by third party agencies, such as gene banks, brokers.
 - Patent applicants seemingly are not responsible for those agencies' violation.
 - **No teeth for disclosure requirement (Art.26 para.5)**
 - The legal consequence for failing to disclose is not serious enough.
 - Better choices: invalidation of patents, or administrative liability .
 - **Chemical synthesis**
 - Chemically synthesized genes or compounds originally isolated or purified from biological materials .

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3, Access to Genetic Resources and Benefit-sharing

- The progress of drafting China's ABS regulation:
 - China is likely to adopt the CBD's approach
- CBD's ex ante approach to biological resources
 - Property Right +Contractual Agreements
 - Re-confirm the ownership of biological resources as tangible property;
 - Base the benefit-sharing requirement on property right (actual control).

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3, Access to Genetic Resources and Benefit-sharing

- **Why is CBD's ex ante approach not a good law?**
 - **Costs for ex ante compulsory PIC and mutually-agreed terms:**
 - **Procedural formalities** before actual access to biological resources;
 - Difficulties in communicating with the provider of resources
 - Only **very few** projects finally achieve commercial success, thus have **distributable benefits**.
 - **Costs for policing the moving of genetic resources:**
 - Once genetic resources were out of the control of a contractual party, the protection would be over.
 - When multiple parties have access to a genetic resource, it is hard to know who is breaching a contract by supplying the resource to a third party.

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3, Access to Genetic Resources and Benefit-sharing

- **Why is CBD's ex ante approach not a good law?**
 - **Loopholes:**
 - Those who do not seek IP protection: no benefit-sharing?
 - When the term of protection for intellectual property protection expires ;
 - Third party who use the technologies relying on genetic resources.

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3, Access to Genetic Resources and Benefit-sharing

- **A better alternative?**
 - **Property right + *Sui generis* right: an ex post approach**
 - Create a sui generis right on biological resources to exclude a third party from commercializing inventions relying on genetic resources .
 - Copyright-alike protection, no registration needed. (anti-copying)
 - Sui generis right and property right co-exist in genetic resources.
 - Access to genetic resources is subject to traditional rules of property law, not the sui generis legislation .

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3, Access to Genetic Resources and Benefit-sharing

- **A better alternative?**
 - **Compared with CBD's approach:**
 - No mandatory prior informed consent
 - No ex ante benefit-sharing agreements
 - Free to seek intellectual property protection
 - Free to trade genetic resources (subject to rules of property law)
 - May need to disclose the source or origin of genetic resources

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4, Traditional Knowledge

- **Definition:**
 - WIPO: not workable at all.
 - TK refers to the content or substance of knowledge resulting from intellectual activity in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources. *“Revised provisions for the Protection of Traditional Knowledge Policy Objectives and Core Principles” WIPO/GTRKF/IC/9/5 (2006)*
 - For purpose of this presentation:
 - Only knowledge having technological utility;
 - Regardless of whether it is related to GR or not.

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4, Traditional Knowledge

- **Types of traditional knowledge and possible models for its protection (my method of classification)**
 - TK privately-held
 - Trade secret model + patent model, no better choice
 - TK held by small communities or groups
 - Trade secret model + patent model, maybe.
 - May loosen the requirement for secrecy.
 - TK in public domain (well-known to the general public)
 - Some moral rights, possible.
 - No cost-effective model to protect
 - Unfortunately, most advocates mean this type when talking about TK.

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4, Traditional Knowledge

- **Difficulties in recapturing TK in public domain**
 - **How to justify TK protection in domestic context:**
 - A property right based on its owner's special social identity ?
 - Usefulness or Utility itself is not a justification: All basic scientific knowledge is useful , but no protectable.
 - Direct finance aid to marginalized minority group should be more cost-effective than protecting their TK.
 - **How to reconcile the TK protection with patent law?**
 - Inventions based on TK have a limited term of protection.
 - When the term expires, inventions will come into public domain or not?
 - The free availability of a technology in public domain would be threatened.
 - An Improvement to TK is still a TK or modern invention? Which model to protect it ?

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4, Traditional Knowledge

- Difficulties in recapturing TK in public domain (*cont'd*)
 - How to prove copying: the linkage between TK and derivative inventions
 - Patent law: “all elements rule”
 - TK protection: “inspiration from TK “ is not easily traceable.
 - If not “all elements rule”, where is the end?

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4, Traditional Knowledge

- Difficulties in recapturing TK in public domain (*cont'd*)
 - Threat to the competitiveness of local research industries:
 - Joint research projects between international companies and local labs
 - An Example: Traditional Chinese Medicine, to compete with Japan, Korea, Singapore, Hong Kong, and all other countries with significant oversea Chinese presence!
 - Other difficulties:
 - The ownership of TK:
 - cost for distributing the benefit
 - When the delineating cost exceeds the benefit, no entitlement is more efficient.
 - The term of protection:
 - Permanent protection?
 - Shall we assume that no one would re-invent a TK?

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The End !

Thanks for your attention!



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