Prevention and Management of Bio-Piracy of Genetic Resources from the Perspective of Intellectual Property

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Abstract. The paper collected cases of bio-piracy in agricultural and medical fields by literature search and database query. Through the analysis of bio-piracy, we propose an intellectual property management system against bio-piracy of genetic resources based on legal and managerial loopholes in China’s genetic resources protection. Both government administration and enterprises’ strategy in intellectual property management should be enhanced to legally share the benefits of genetic resources and to protect biodiversity.

Current Status of Bio-piracy at Home and Abroad

Bio-piracy is a term coined by Rural Advancement Foundation International (RAFI) in 1994 on the basis of bio-prospecting to refer to a fraudulent act in bio-prospecting [1]. Bio-piracy is an unregulated patenting of indigenous knowledge obtained unethically. Some transnational corporations or foreign research institutes collect and utilize the indigenous knowledge and genetic resources in pursuit of monopoly and profits, without providing any compensation or sharing the benefits with indigenous peoples from whom the biological information is obtained. Instead of adding to the existing body of biological knowledge, bio-piracy is merely more than plunder and plagiarism and contributes little to global technological advancement. So bio-prospecting is essentially different from bio-piracy. Developed countries claim that biological resources and genetic resources are commonly shared by all human beings and that not a single country enjoys sovereign rights to biological resources [2]. This is little more than a justification.

Along with the development of biotechnology, genetic resources are considered important strategic resources of a country. However, genetic resources are also the targets of pillage. Looting of biological resources is a smokeless war. China possesses rich biological resources and may fall prey to the plunder by developed countries. Therefore, it is of utmost importance to enhance the protection of China’s biological resources against bio-piracy.

A survey conducted by RAFI, an NGO in 1998 indicated that the biomaterials germplasm bank among at least 140 cases was directly plagiarized by a foreign company or research institute without any modification or processing. The products developed from such biomaterials are patented in the foreign countries or locally to reap high profits. In contrast, the countries where the biomaterials are obtained are denied a single share of the profit. Rather, exports of these countries are restricted during to intellectual property protection, which result in unsalable products and huge fines.

China is no exception when it comes to bio-piracy. China, which enjoys abundant genetic resources, is one of the top twelve countries with the highest biodiversity. A large amount of species with excellent economic values are bred or domesticated by Chinese people. Different lifestyles and rich species have been passed down through generations among different ethnic groups in China, which further enriches the genetic resources. Some remote regions inhabited by ethnic groups are rarely interfered by external factors and there is very little migration. Therefore the purity and originality of genetics are well preserved in these regions. The features make China an easy prey to bio-piracy, and many cases of bio-piracy have already happened. For example, Monsanto Company applied for an international patent relating to the breeding and detection of high-yield soybean in 101 countries including China on April 6th, 2000. This is the so-called
Monsanto Event. The key biomaterials for this patent come from China’s wild soybeans. Chinese farmers who have grown soybeans for thousands of years may easily violate the patent without them even knowing it. China already pays a great deal because of this patent, and some soybean products cannot be exported due to international trade sanctions. Such crises will likely befall China’s other biological products and threaten national economic safety if no appropriate measures are taken against it.

Prevention and Management of Bio-piracy in India

India is also a developing country that possesses abundant genetic resources. In recent years, India has gained rich experiences in the prevention and management of bio-piracy.

Legislation

India’s Patent Law for the Protection of Genetic Resources. According to U.S patent law, public use and sales are not considered the criteria of disclosure. This is apparently an encouragement of bio-piracy. As a counterattack, India revised the Patent Law on December 26th, 2004. It is specified that if the conventional knowledge utilized in the patented products is common knowledge, then any use of this knowledge is illegal without informed consent from the indigenous people from which the knowledge is obtained. This revision attempts to enhance the protection of genetic resources and to forbid illegal patenting of products related to bio-piracy.

Protection of Genetic Resources under Convention on Biological Diversity (CBD). India is one of the countries that were once inflicted by bio-piracy. After a series of cases related to bio-piracy of neem tree, tumeric, and basmati tree, the general public made a strong appeal to the Indian government and demanded the enactment of laws and policies to stop bio-piracy. Learning the lessons of the past, Indian government resists bio-piracy from multiple pathways. After fully realizing the potential protection offered by CBD, India, as a contracting state of CBD, began to take advantage of the rights and opportunities to profit from genetic resources and conventional knowledge. Rajya Sabha passed the Law on Biodiversity on December 11th, 2002. To safeguard the benefit sharing mechanism, India latter passed the Rules on Biodiversity in 2004, which stipulates that the amount of benefit sharing should be negotiated with local institutions and stakeholders.

Supportive Administration

Establishing Governmental Authorities in Charge of the Protection of Genetic Resources. Committee on Herbal Protection is intended to rescue the medicinal plants being overexploited. Each state is encouraged to build herbal protection zones to prevent ruthless exploitation of Indian herbs and species extinction, while improving the performance and effectiveness of herbs. In addition, a three-level managerial system was established according to the Law on Biodiversity, namely, national bureau for biodiversity, state bureau for biodiversity and committee on biodiversity management. Take the national bureau for biodiversity as an example. National bureau for biodiversity is responsible for handing all patent applications for inventions based on genetic resources that are submitted by non-Indian citizens, legal persons and organizations. Application for intellectual property right is not allowed within and outside India without the approval from the national bureau for biodiversity.

Building Biodiversity Registration Management System. In order to suppress any form of violation, India has built the biodiversity registration management system open to the general public. The main contents of the biodiversity registration management system are as follows: Knowledge related to species, usage and expertise; natural knowledge related to biodiversity; ecological knowledge. Detailed information of the right holder should be provided during registration. Therefore, the right holders can make claims for loss of damage when other persons use the patented knowledge without prior permission or when the right holders do not share the benefits brought by the knowledge.

Building Digital Library. India built Traditional Knowledge Digital Library (TKDL) in 2001. The first phase of building was completed in August 2003. TKDL gathers traditional knowledge
scattered to different social classes. TKDL contains the knowledge of traditional Indian therapies and over 900 Yoga postures. At present, the United Nations, European Patent Office and United States Patent Office have been authorized to use TKDL. When a patent application for Indian conventional knowledge is submitted, the patent examiner will search TKDL to see whether the applied patent is different from the registered knowledge. TKDL provides a link between the scattered indigenous medicinal and herb knowledge and contemporary economic development via international retrieval. TKDL is an effective tool for resisting illegal use of conventional knowledge, usually in the form of hegemony and monopolistic exploitation by transnational companies. [3]

**Current Status of Bio-piracy Prevention and Management in China**

**Domestic Legislation**

China’s protection of genetic resources lags behind due to various factors, though some interim progress has been made. China’s laws on genetic resources protection are divided into three levels. The top-most level is the Constitution. The 9th and 26th clauses of the Constitution revised in 2004 address the protection of genetic resources. The Constitution is the fundamental law of China and the highest law on genetic resources protection. The second level consists of Patent Law and Criminal Law. The Patent Law revised in 2008 marks a milestone in the actions against bio-piracy. The revision mentions bio-piracy for the first time and set forth the requirement on the legitimacy and disclosure of origin of genetic resources. The third level consists of administrative laws and regulations on genetic resources protection, including Regulations on Protection of Wild Medicinal Resources, Regulations on the Protection of New Varieties of Plants, and Administrative Measures for Livestock and Poultry Genetic Resource Preserving Farms and Gene Bank.

**Drawbacks**

Firstly, there is no special law for genetic resources protection. Most of the regulations are only principles, or separate laws for different species and districts. As a result, some laws are repetitive or in conflict with each other, while other important areas are not covered by laws.

Secondly, China is a contracting country of CBD, but the basic principles of CBD are not fully embodied or utilized in Chinese laws. China achieves much less in the prevention against bio-piracy compared to India, and Chinese laws lag far behind in this regard.

Thirdly, although genetic resources protection was first mentioned in the Patent Law revised in 2008, no detailed or explicit definition has been given to genetic resources. There is neither emphasis on sovereignty of genetic resources, nor specification on the application scope, reviewing authorities, and contents of review relating to the disclosure of the origin of genetic resources. No benefit sharing mechanism relating to genetic resources is available. Therefore, the clauses of Patent Law concerning genetic resources protection in China lack operability and feasibility.

**Prevention and Management Measures**

**Building High-Efficiency Genetic Resources Database**

Building a high-efficiency genetic resources database will aid the retrieval work for the patent examination authorities. Applications that do not meet the patentability requirement are directly turned down, which saves time and increases the patent examination efficiency. Even if some unqualified patents are granted, the information in the genetic resources database can serve as powerful evidences for patent invalidity and revocation. This also represents a counterattack against US's operation of a mixed novelty system by repudiating bio-piracy. Large-scale genetic resources database is usually based on extensive collection and preservation of valuable biological genetic resources and exploration of the relationship between environment and creatures. This will further facilitate the protection and monitoring of species diversity and ecosystem.
Setting up Special Laws and Administrative Authorities in Charge of Species Diversity and Genetic Resources Protection

It has been emphasized in State Council Issues Outline of National IP Strategy that revision of patent law, trademark law and copyright law and legislation in protection of genetic resources, conventional knowledge, folk literature and art and geographic indications must be enhanced. Specifically, legislation in protection of genetic resources takes sustainability as the fundamental purpose, while combining the principles of safeguarding state sovereignty, benefit protection and diversification of benefit sharing. The contents of legislation include defining scope of application of law, specifying administrative authorities, examination and approval procedures, and compensation measures, so as to achieve a fair sharing and exploitation of genetic resources.

Perfecting Patent Law

Definition of Genetic Resources. The second clause of CBD defines genetic resources as genetic materials that have actual or potential values. Genetic materials are those that come from plants, animals and microorganisms or any other sources that contain functional genetic units. China signed CBD in 1992, and on reserve clauses apply to CBD in China. Therefore, the above definition of genetic resources is applicable to China and should be incorporated into the Patent Law [4].

Establishing State Sovereignty over Genetic Resources. One of the most common justifications of bio-piracy used by developed countries is that genetic resources are shared by all human beings. Not a single country can claim sovereignty and exclusive right over genetic resources. From this perspective, an important aspect of the fight against bio-piracy is to gain recognition of state sovereignty over genetic resources. By doing this, “bio-prospecting” without prior permission naturally becomes an act of piracy or loot. Moreover, the countries of origin will be fully justified in state administration and control of illegal exploitation of indigenous resources by foreign countries.

Prior Informed Consent and Benefit Sharing Mechanism. Prior informed consent: First of all, examination and approval authorities should be set up to take charge of patent examination and surveillance. Contents of administration and supervision include registration of genetic resources, examination, approval and consent of acquisition and exploitation of indigenous genetic resources by foreign researchers or institutes, negotiation with stakeholders, and ex-post supervision of the exploitation act. Secondly, the type, scope and purposes of application of genetic resources that are allowed should be specified in details. Moreover, the procedures of applying for prior informed consent must be also detailed.

Benefit sharing mechanism: Building a benefit sharing mechanism is the ultimate goal of cracking down bio-piracy and setting up a genetic resources disclosure system. This mechanism enables a reasonable benefit sharing between the “pirates” and countries of origin from the inventions that are based on indigenous genetic resources. This mechanism should specify the types and forms of benefit sharing, obligations and responsibilities of uses and countries of origin, definition and sharing of interests arising from the use and transfer of genetic resources, as well as the compensation due to unauthorized exploitation.

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