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PLANT BIOTECHNOLOGY INTELLECTUAL PROPERTY RIGHTS AND THE BT COTTON CASE IN CHINA

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IPR PROTECTION IN CHINA: A GENERAL REVIEW

The modern intellectual property system in China was developed only since the early 1980s as a result of the economic reform and opening-up of China's economy to the rest of the world. In 1980, with the approval of the State Council, the Chinese Patent Office (CPO) was founded to be the sole patent administration at state level. In 1998, the CPO was reconstructed and renamed as the State Intellectual Property Office (SIPO), which is directly under the State Council. At present, the SIPO is mainly in charge of patent affairs and serves also as the coordinating authority for foreign-related intellectual property right (IPR) issues.

On June 3, 1980, China acceded to the *Convention Establishing the World Intellectual Property Organization*. Additionally, regarding the patent issue alone, China is now a member state of the *Paris Convention for the Protection of Industrial Property*, the *Patent Cooperation Treaty* (PCT), the *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure*, the *Locarno Agreement Establishing an International Classification of Industrial Designs*, and the *Strasbourg Agreement Concerning the International Patent Classification*. Since January 1, 1994, after becoming a member state of the PCT, SIPO has been serving as the Receiving Office of International Searching Authority and International Preliminary Examining Authority, and the Chinese language is now one of PCT's working languages.

Under the guidance of SIPO, besides the CPO, there are two main administrations, i.e., the Trademark Office (temporarily being under the State Administration for Industry and Commerce) and the State Copyright Office, who are responsible for administration of trademark and copyright issues, respectively.

Regarding the patent law legislation in China, the Patent Law was first adopted by the National People's Congress on March 12, 1984, entered into force on April 1, 1985, and has been amended twice in 1992 and 2000, respectively. Meanwhile, in accordance with the Patent Law, the Implementation Regulations for the Patent Law have also been issued and amended accordingly.

For the issue of new plant variety protection, upon becoming the 39th member country of UPOV, China has issued its Regulations on the Protection of New Varieties of Plants in 1997 and entered into force on April 23, 1999.

This paper summarizes our survey of the current situations of patent application in the field of genetic engineering. Section I provides the current situation of IPR protection for genetic engineering and plant variety rights protection; the problems and challenges met in IPR management will be discussed in Section II; and Section III provides the Bt cotton case study. The concluding remarks are provided in the final Section.

SECTION I: CURRENT BIOTECHNOLOGY IPRS IN CHINA

1.1 Patents on Genetic Engineering

With the fast increment of patent applications in the field of biotechnology in China, a Division for Biotechnological Inventions Examination within the CPO was specifically set up to meet the needs of increasing patent application on biotechnology. This Division mainly deals with the applications and examinations of genetic engineering patents. In addition, an

IPR Affair Center under the Ministry of Science and Technology was set up in 1995 as a governmental consulting agency for IPR issues in China (SIPO, 1999).

The data presented by the SIPO show that, from April 1, 1985 to the end of 2000, about 1265,974 patent applications have been filed in the CPO, with 687,541 patents granted during that time. It is shown that, in the 1990s, the number of patents on genetic engineering is ranked among the top 20 groups, with however as low as about one percent of the total patents granted (SIPO, 2000). But on the other side, as our figure and data indicate, the number of patent applications on genetic engineering has been increasing overtime, particularly after 1998.

Further analysis shows that multinational companies filed the most applications in genetic engineering in 1985-1998. An average of 90% applications were from foreign companies in this period. Among the patent applications filed in the CPO on genetic engineering, about 75% of them were filed by foreign entities (companies or institutes. Comparatively, applications submitted by Chinese scientists accounted for 25% only. Compared with foreign companies, the percentage of domestic application on genetic engineering is less than 10% in the first five years since the Patent Law was enforced (1985 to 1989). However, domestic applications have increased dramatically since 1998, and surpassed the foreign applications to account for 55% of the total applications in 1999 and more than 90% thereafter. The major reason lies in the huge amount of application by the United Gene Holdings LTD (United Gene for short), a pharmaceutical company established in 1997 by two professors from FuDan University, Shanghai. United Gene filed 240,2940 and 188 applications for gene invention in 1999, 2000 and 2001, which accounted for 25.6%, 85.3% and 34.3% of the total annual applications, in this subject area. All of these applications were in the field of pharmaceutically related genes, technology or products. In the year of 2000 alone, the patent application reached up to 3447 cases, which accounted for 51.3% of the total applications in the period of 1985 to 2001. This result may link with the enforcement of the new amended Patent Law.

The top ten countries accounted for about 92% of the total foreign applications filed in the CPO in 1985-2001, which includes the USA, Japan, Germany, UK, Switzerland, Denmark, France, the Netherlands, Canada, and Australia. Depending on its advancement of biotechnology industry, USA becomes the top country in applying gene patents in China, accounting for 39.7% of the total foreign applications in the period of 1985 to 2001.

It is shown that the majority of patents on genetic engineering are within the field of pharmaceutical and agriculture. The former accounted for 72.7% and the later accounted for 8.9% in 1985-2002. This might reflect the fact that pharmaceutical products, produced in confined factories, are easy to be protected. On the other hand, the benefits returned from pharmaceutical products may be more direct than those on agricultural products.

1.2 Protection of New Varieties of Plants in China

In China, it’s the Plant New Variety Protection Office under the Ministry of Agriculture (MOA) and State Forest Agency (SFA) that is responsible for granting Plant New Variety Right. The administrating system for PVP was established in 1999. The MOA is responsible for granting rights for the agricultural crops, such as grain, cotton, oil plants, hemp plants, mulberries, tea, sugar, vegetable, edible fungi, tobacco, fruit trees (juicy), herbaceous medicinal materials, herbaceous ornamental plants, grass, rubber, and green manure; and the

SFA is in charge of the forestry plants like forest trees, bamboo, xyloid vine, ornamental woody plants, fruit trees (dry), woody oil-bearing, beverage plants, condiment plants, and woody medicinal materials. (MOA, 2001)

MOA has issued five batches of agricultural plants for Plant New Variety Rights since 1999 (MOA, 2003). Totally, there are 39 genera/species of agricultural plants being listed for the protection by the new plant variety protection policy in China (Table 1). MOA has received 1061 applications for Plant New Variety Rights from April of 1999 to August of 2003. Rice and corn are two major field crops for new variety protection, the applications and granting on these 2 crops account for 77% and 80%, respectively (Table 2). Regarding the planting area in China, 50% of rice and 95% of corn are hybrids (Huang Jikun, 1998). Farmers and small seed dealers can't make hybrid seeds by themselves, so that the plant variety rights can be protected sufficiently in hybrids. In terms of the conventional varieties, the Seed Law and Regulations on the Protection of New Varieties of Plants (1978 version of UPOV) protect the farmer's rights, which means Chinese farmers can save the seeds for their own field or exchange crop seeds with other farmers. So the IPR of conventional crop varieties is difficult to be protected by the current Regulations on the Protection of New Varieties of Plants.

A total number of 412 varieties have been granted with the Plant New Variety Right. There are 317 applications from January to August in 2003, while only 172 applications were made in the same period of 2002. The breeders have recognized the importance of Plant New Variety Right, so the application on the Plant New Variety Right is increasing yearly. However, there is still no transgenic plant variety that has been granted by the PVP rights in China.

At the meantime, to strengthen the management to plant new varieties, MOA has established a Propagation Material Preservation Center for Agricultural Plant New Varieties, which is responsible for the quality & quantity detection and preservation of propagation materials. MOA has also established one Center and 14 branch centers for the DUS test of new agricultural plant varieties.

SECTION II: PROBLEMS AND CHALLENGES IN PLANT BIOTECHNOLOGY IPRS

Great achievements have been made on IPR protection for genetic engineering in general and for plant biotechnology particularly in the past twenty years. However, problems and challenges are emerging with the implementation of IPR policies and regulations. The following are some of the obvious examples.

(1) Public Awareness:

During the past 20 years, although both the government and scholars concerned with IPR management and research have done much work on explaining IPR matters. However, there remains less public awareness compared with that in some developed countries. This phenomenon sometimes exists in public research institutes whose fiscal incomes rely significantly on governmental inputs. Some writers have suggested that this can be traced back to the centrally planned economy period (Huang, Jikun, Ruifa Hu, Scott Rozelle, 2003[a]). The main source of investments in biotechnology research in China is the national government (Huang Jikun et al, 2001). Donor agencies contributed between 1.5 percent in 1986 to 6.9 percent of the total plant biotechnology budget for 22 major plant biotechnology institutes surveyed in 1999. It's believed that this recognition of IPR can be improved

through education, training, and information exchange.

(2) Capacity Building on IPR Protection

This aspect may involve several dimensions, such as educational or training programs and fiscal aids. For example, a particular concern of IPAC in MOST is to encourage the scientists to look for more opportunities to protect the technology, processes or products they have developed by patents and other IPRs, if necessary. Policies concerning financial aids or economic benefit have also been adopted.

(3) Implementation on IPR Protection

The legislation on IPR laws has made obvious progresses in the past ten years, especially in the 1990s. But the implementation of the IPR laws is not yet fully completed. This is reflected in both the IPR administration and judicial practice. Monitoring actual implementation of IPR protection is also a difficult task that may be improved in the future.

(4) Emerging Mechanisms for Technology Transfer

Mechanisms of technology transfer are still developing in China, and particularly in the transfer of high technology, such as plant biotechnology. This may affect China's emerging technology market and venture capital activity (especially in agricultural or plant biotechnology). Additional human resources and capacity building would be helpful. The government is now encouraging private funds to enter this field. The cost-benefit analysis is being applied more frequently to evaluate different models of technology transfer.

(5) Enforcement of Laws and Regulations

Although the IPR legal system has been established in China, the unauthorized use of IPR protected plant biotechnology occurs frequently.
There have been many reported illegal transactions, which may infringe a patent right or a plant breeder's right. This may involve some small seed companies or the farmers themselves. Therefore, how to check the infringement and at the same time balancing farmers' right is a challenge in China as well as in other countries. Regional concerns may in some instances affect the settlement of legal disputes because local government may put the conduct accused of infringement under their protection.

SECTION III: THE BT COTTON CASE STUDY

Under the support of the National High-Tech Program, the so-called "863 Plan", a great breakthrough has been made in the research and development of transgenic cotton resistant to cotton bollworm. *Bacillus thuringiensis* (Bt) and Cowpea Trypsin Inhibitor gene (CpTI) have been modified, synthesized and transferred into a few dozens of cotton cultivars, which have been approved by the Biosafety Committee at the Ministry of Agriculture for commercialization in China since 1997. The key technology of insecticidal gene's synthesization, vector construction and pollen tube pathway transformation method was patented in China in 1998, and it was granted as the "Golden Award for Patent" by the WIPO and SIPO in 2001. Upon this patent, China becomes the second country in the world to successfully develop Bt cotton with its own IPRs.

Bt cotton is the transgenic crop with the largest commercial area in China. Thirteen transgenic cotton varieties and 5 transgenic cotton hybrids have been registered and commercialized in 12 cotton production provinces. The accumulative total area of Chinese transgenic cotton (exclude Bt cotton area from Monsanto) by 2003 was 3.4 million ha.

Bt cotton not only increases the yield, but also reduces the spry of pesticide and labor input, therefore Bt cotton has dramatic economic and social impact. According to Jikun Huang's field survey (Jikun Huang et al, 2003[b]), in the provinces that still grew some non-Bt cotton in 2001, the mean yield of the Bt cotton varieties is 17% higher than that of non-Bt varieties in 2000 and 6 to 7 percent in 2001. Chinese Bt cotton farmers reduced pesticide use by an average of 13 sprayings (49.9 kg) per hectare per season (Jikun Huang et al, 2002). This reduced $762 of cost per hectare per season. Farmers also significantly reduced labor for pest control. According to Jikun Huang's estimate the total benefit from the adoption of BRI (Biotechnology Research Institute, Chinese Academy of Agricultural Sciences) Bt cotton in 1999 alone was $197 million (Jikun Huang et al, 2002). More than 5 million farmers have adopted Bt cotton in China.

Concluding Remarks

This paper gives a review for the IPR in general and that of the plant biotechnology in particular, together with a description of the Bt Cotton Case. The legal system for IPR protection in China has been established. Patent applications on genetic engineering are increasing year by year. During the period of 1985 to 1998, multinational companies filed the majority of patent applications in China, but with the establishment of United Gene, the domestic application increased dramatically from 1999. Although there is no transgenic plant granted by PVP, great progress has been made in non-transgenic plants for PVP, particularly for hybrid rice and corn in China. Through patents and PVP, plant biotechnology can be protected in China now, but the situation is far from being satisfactory. Various problems and challenges concerning IPR protection in China still exist with the rapid development of biotechnology. To solve or minimize the current problems, the capacity building, legal system and enforcement of Laws and Regulation on IPR protection need to be further improved. Bt cotton is the only transgenic crop with large commercial areas in China, and the commercialization of Bt cotton has achieved great positive impacts on farmer's income and environmental protection.

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Table 1. Protected botanical genera and species of plants by the MOA

Issue date	Plant species
June 16, 1999	Rice, maize, Chinese cabbage, potato, spring orchids, chrysanthemum, Chinese Pink, clover, grass
March 3, 2000	Wheat, soybean, oil rape seeds, peanut, tomato, cucumber, chili, pear, dock
Feb. 26, 2001	Orchids, lily, bird of paradise, sea lavender
Jan. 4, 2002	Sweet potato, millet, peach, Litchi, water melon, cabbage, radish
July 14, 2003	Broomcorn, barley, ramie, apple, citrus, banana, kiwi fruit, grape, plum, eggplant

Table 2 Summary of applications and granting for Plant New Variety Rights on agricultural plants

Plant species		1999.4 – 2003.8		Application	
		Application	Granted	2002	2003
Field crops	Rice	318	82	38	141
	Corn	499	248	68	95
	Soy bean	29	19	2	6
	Wheat	69	22	23	28
	Brassica	36	11	8	17
	Peanut	10	5	1	3
	Sweet potato	2	0	0	2
Vegetables		60	14	20	16
Flowers		11	0	2	3
Fruit trees		26	11	10	6
Pasture		1	0	0	0
Total		1061	412	172	317

* Data provided by Plant New Variety Protection Office, MOA, 2003

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