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# Who Owns the Intellectual Property Rights to Chinese Genetically Modified Rice? Evidence from Patent Portfolio Analysis

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## I. INTRODUCTION

On August 17, 2009, China's Ministry of Agriculture (MOA) issued biosafety certificates for commercial production of two genetically modified (GM) rice varieties—*Bt* Shanyou 63 and Huahui 1—to the Huazhong Agricultural University. The certificates are valid from August 2009 to August 2014, during which time, the two GM rice varieties are allowed to grow on farmland in central China's Hubei province.[1] For a while, China, the world's largest rice producer and consumer, was expected to become the first country to produce GM rice, a major staple food crop, which would likely positively impact global acceptance and accelerate the adoption of biotechnology food crops (James, 2009). Although the GM rice varieties still need to undergo the administrative test on value for cultivation and use (VCU), as well as pass crop variety registration (which usually takes 2 to 3 years), the landmark decision in China's regulation of the commercialization of GM crops immediately spurred public debate. In fact, the commercialization of GM rice has become the subject of controversy. In addition to the caution over the possible adverse impacts of GM varieties on the health of human beings and the environment, there have been concerns about the ownership of the intellectual property (IP) on the GM rice developed in Chinese laboratories (Zhou *et al*., 2008). The question—who owns the intellectual property rights (IPRs) of the Chinese GM rice—is still lingering in China.

The concerns about the IPRs of the Chinese GM rice were first raised by Greenpeace, the international environmental protection non-governmental organization (NGO), which largely opposes biotechnology activities. Around the time the biosafety certificates were granted to the GM rice varieties of *Bt* Shanyou 63 and Huahui 1, Greenpeace issued two major reports, claiming that the Chinese-developed GM rice may fall into the "foreign patent trap," as these rice varieties may have used patents owned by foreign entities. In particular, in the first report, Greenpeace declared that at least 11 to 12 patented or proprietary methods and materials associated with three varieties of Chinese GM rice may belong to major international agribusiness companies (Greenpeace and TWN, 2008). In a follow-up report, Greenpeace concluded that another five Chinese GM rice varieties under development may have used at least 10 foreign patents (Greenpeace and TWN, 2009). Both reports implied that the Chinese GM rice would fall within the scope of foreign patent protection. Furthermore, Greenpeace argued that commercialization of GM rice in China would represent a threat to China's food security, sovereignty, food prices, and small-holding farmers' livelihood. Once exported, according to Greenpeace, these GM

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[1]The second-round list of the safety certificates of agricultural GMOs approved by MOA in 2009 is *available online at* www.stee.agri.gov.cn/biosafety/spxx/t20091022_819217.htm (last accessed 20 February 2013).

rice varieties would be subject to international IP laws, thus exposing China's rice-growing farms and the entire rice industry, including the rice seed and hybrid rice seed industries, to the control of foreign patents. Moreover, the foreign patent holders could demand royalties and compensation from China, and the big GM seed companies would stand to take the most benefits, while Chinese farmers would lose because they could not go back to conventional, non-GM seeds (Jia, 2010). The Greenpeace reports mentioned further hidden risks associated with undisclosed biological material transfer agreements that Chinese GM rice developers may have signed with foreign IPR holders. The GM rice under the Greenpeace's scrutiny includes the *Bt* varieties for which the Chinese government authorized commercialization.

The Chinese government and Chinese researchers involved in the development of GM rice have not only disputed Greenpeace's conclusions, but also repeatedly claimed that the Chinese GM rice varieties have been developed using China's own materials and technology, so as to allow domestic ownership of IPRs. For example, on July 9, 2010, the Office of Agricultural Genetic Engineering Biosafety Administration (OAGEBA), an organization affiliated with China's MOA, declared on the MOA website that both *Bt* Shanyou 63 and Huahui 1 had been developed with indigenous Chinese techniques and would not infringe any in-force patents filed in China.[2] This official position was reaffirmed by a report issued by the State Intellectual Property Office (SIPO), China's patent office. The SIPO report specifically mentioned that it had granted the inventors of the Huahui 1 a patent entitled "The breeding methods of GM rice" (Patent No: ZL200510062980.9).[3] In the meantime, some Chinese legal scholars have discounted the possibility that a significant risk of lawsuits may exist during the commercialization of Chinese GM rice on the ground that China has been trying to develop many indigenous innovations and technologies (Liu and Li, 2010; Liu, 2012).

Indeed, there are serious deficiencies in the Greenpeace reports. First, the research lacks scientific evidence and legal basis. Through searching all GM-related patents in the United States Patent and Trademark Office (PTO) and European Patent Office (EPO) databases, this Greenpeace commissioned research identified some patent applications with similar topics and then speculated arbitrarily that the Chinese GM rice would be covered by these foreign patents.[4] Second, the reports completely ignore the nature of patent protection in terms of time frame, geographical coverage, and judicial scope of the patent rights. For example, the research does not look into whether any patent at stake has been filed and—especially—granted in China, and if so, whether it is still valid. Third, and most importantly, the Greenpeace research absolutely neglects the applicability of foreign patent claims to commercialization of Chinese GM rice as these foreign patents are not granted in the major rice producing, exporting, importing, and consuming countries.

Of course, the Chinese government and Chinese legal scholars have not, for their part, examined thoroughly whether China owns the full IPRs to its GM rice. In sum, neither opponents nor supporters have obtained all the information that could shed light on the complexity and dynamism of the IP framework in biotechnology research in general or pertaining to IPRs in the research and development (R&D) of Chinese GM rice in particular, because of the confidential terms of contracts between the parties involved.

In this paper, we try to answer the question of the ownership of the Chinese GM rice through analyzing patent portfolio of *Bt* Shanyou 63, one of the approved GM rice varieties. *Bt* Shanyou 63 is also a hybrid of Zhenshan 97A (cytoplasmic male sterile [CMS] line) and Huahui 1, a restorer for the CMS line. In particular, the paper reviews the IP and technical property components associated with China's GM rice with the objectives of (i) examining the distribution and structure of patent rights on China's GM rice; (ii) assessing the extent to which China owns the IPRs to the GM rice; (iii) evaluating the impacts of relevant patents owned by foreign holders; and (iv) identifying the possibility of patent infringements if China commercializes its GM rice. The research is based mainly on patent portfolio analysis by investigating the distribution of patents, particularly the coverage and strength of patent claims. The data have been obtained from the PTO and EPO patent databases that have been used in the Greenpeace research, as well as from the SIPO patent database. A number of professional queries based on a combination of international patent

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[2]Announcement on the intellectual property rights issues of insect-resistant GM rice and phytase maize is *available online at* www.moa.gov.cn/ztzl/zjyqwgz/zswd/201007/t20100717_1601272.htm (accessed 20 February 2013).

[3]SIPO (2010, March 23). The argument that GM crop patents controlled by foreign companies is not right. *Legal Daily* [Fazhi Ribao], p. 6.

[4]While acknowledging Li Hui and Christoph Then, respectively, in research, the Greenpeace reports do not indicate who had been commissioned to do the research.

classification (IPC) codes and technology-related search terms will be explored to collect all relevant IP documents. In addition, some relevant scientific publications from the Web of Science will be referenced accordingly. The research results will provide a basis for reconsidering the questions of commercialization of GM rice in China and reviewing China's strategic R&D policy in agro-biotechnology from the IP perspective.

The rest of the paper is structured as follows. Sections 2 and 3 describe the R&D of GM crops, especially GM rice, and patenting activities in China, so as to provide the historical and institutional contexts of the development of GM rice. Section 4 systematically deconstructs technical components of *Bt* Shanyou 63. Section 5 examines the scope of patent protection of GM rice varieties, and in particular, whether the production of the Chinese GM rice is covered by foreign patents. Section 6 discusses the implications of the results for the IP management of GM rice as well as other GM crops in China and elsewhere.

## 2. GM CROPS IN CHINA—POLICY, RESEARCH AND DEVELOPMENT, AND COMMERCIALIZATION

During most of the past three decades, China has maintained a positive attitude toward the development of genetically modified organisms (GMOs) (Paarlberg, 2001). In fact, China has bet on GM crops, hoping not only to meet its increasing demands for food with higher yields, better nutrition, and broader resistance to pests and diseases, in order to ensure food security and alleviate the huge problems of pollution from pesticide use, but also to become a global leader in agricultural biotechnology (Huang *et al*., 2010). Its efforts in developing GM crops started in 1986 when the State High-Tech Research and Development Program (also known as the 863 Program) included biotechnology as one of its priorities. The State Basic Research and Development Program (also known as the 973 Program), launched in 1997, and the National Natural Science Foundation of China have allocated resources to basic research underlying agricultural biotechnology (Zhang, 2001). The Rockefeller Foundation, the McKnight Foundation, the China–European Union Science and Technology Cooperation Program, among others, have also supported China's research on GM technology.

In particular, China's public R&D expenditure on GM plants was RMB51 million (US$16 million) in 1986, increasing to RMB996 million (US$120 million) in 2003. Most significantly, in 1999, the State Council approved the initiation of the State GM Plant Research and Commercialization Special Program, with an expenditure of RMB50 million (US$6 million), thus formally beginning the process of commercializing GM crops in China. In the area of GM rice, public research expenditure increased from RMB8 million (US$1.18 million) in 1986 to RMB195 million (US$28.68 million) in 2003 (Huang *et al*., 2008). The program resulted in 1,024 papers, with 264 published in journals catalogued in the *Science Citation Index*, a database compiled by the Institute for Science Information in Philadelphia, now part of Thomson Reuters.[5] In the 10th Five-Year Plan (2001–2005) period, while continuing its emphasis on scientific research, China also furthered its efforts to commercialize the research. The investment into agricultural biotechnology increased to US$500 million by the end of 2005.[6]

In 2006, China's State Council released the Medium- and Long-Term Plan for the Development of Science and Technology (2006–2020) (MLP) as the nation's roadmap to become an innovation-oriented nation (Cao *et al*., 2006). The MLP listed GMO new variety breeding among the 16 Mega-Engineering Programs (MEPs). Started in late 2008, the GM MEP is expected to spend some RMB26 billion (US$3.8 billion) on R&D and commercialization of GM technology during the plan period, with GM rice being selected as one of the priorities. In October 2010, when the Plan for the Development of China's Strategic Emerging Industries was launched, agricultural biotechnology was again identified as a priority.

With strong government support in terms of policy and funding, various initiatives have paved the way for not only research into, but also the commercialization of, GM crops. As a whole, while several locally developed GM crops (including sweet pepper, papaya, and poplar) have been approved and planted, only *Bt* cotton has been cultivated widely, with significant benefits going to Chinese cotton farmers (Huang *et al*., 2010; Wang and Johnston, 2007).

Since the mid-1980s, Chinese scientists have developed many experimental GM rice lines with such traits as higher yield, better nutritional quality,

[5]"China Becomes World's Fourth Largest Country in Terms of Land Sown to GM Plants" (in Chinese). *Available at* http://news.xinhuanet.com/st/2003-07/29/content_999146.htm (accessed 10 January 2013).

[6]*Available at* http://english.mofcom.gov.cn/aarticle/newsrelease/counselorsoffice/westernasiaandafricareport/200503/20050300020580.html (accessed 8 May 2013).

Table 1. Chinese GM Rice Lines Currently Approved for Field Testing or in Development

| *Trait(s)* | *Cultivar(s)* | *Developer* | *Regulatory Status* |
|---|---|---|---|
| Pest resistance | Bt Shanyou 63<br>Huahui No. 1 | Huazhong Agri. Univ. | Biosafety certificate issued |
| | Xiushui 11 | Zhejiang Univ. | In development |
| | Minghui 81 and Minghui 86 | Inst. of Genetics and Developmental Biology, CAS | |
| | IR 72GM Minghui 63 and Maxie 63 | Huazhong Agri. Univ. | |
| | Zhongguo 91 | Shandong Agri. Univ. | |
| | D297B | Sichuan Agri. Univ. | |
| | Zhuxian B | Sun Yat-sen Univ. | |
| Herbicide resistance | Jingyin 119 | China National Rice Res. Inst. | In development |
| | 87203Eyi 105 | Shanghai Jiaotong Univ. | |
| | Xiushui 11Qiufeng Youfeng and Hanfeng | Shanghai Inst. for Biological Sciences, CAS | |

**Sources:** Wang and Johnston (2007), Jia (2010).

disease and insect resistance, herbicide resistance, salt and drought tolerance, and production of pharmaceuticals. In particular, some of these lines have transformed genes from *Bt* that code for insecticidal Crystal (*Cry*) proteins into local rice varieties to develop insect-resistant GM rice, which includes *Bt* Shanyou 63 and Huahui 1. Scientists at public research organizations have also made efforts to establish close partnership with private firms (Zhang *et al*., 2006). Research has shown that Chinese small and poor farm households could benefit from adopting GM rice by both higher crop yields and reduced use of pesticides, which also contributes to improved health. For instance, insect-resistant GM rice produces 6–9% higher yields than conventional varieties, along with an 80% reduction in pesticide usage and a corresponding reduction in pesticides' adverse health effects (Huang *et al*., 2005).

According to China's biosafety regulation policy for agricultural GMOs, commercialization is overseen by the MOA. Like other GM crops, GM rice must go through three phases of biosafety trials—field trials, environmental release trials, and preproduction trials—before a biosafety certificate for commercialization can be issued. Although dozens of GM rice lines have been developed, only two lines—KMD1 and KMD2 transformed with a synthetic *cry1Ab* gene—were evaluated in the field trial in 1998 (Chen *et al*., 2011). As of 2005, more than 100 GM rice varieties and hybrids—mostly insect-resistant ones—had been in field trial (Wang and Johnston, 2007). It is only when the GM rice was singled out as one of the areas for the development in GM crops in the MLP was the long-delayed biosafety approval process accelerated, which finally led to the granting of biosafety certificates to the GM rice varieties, as well as that of phytase maize in 2009. However, many other GM rice lines that have been developed and extensively tested are still awaiting biosafety approval (Table 1).

Soon after receiving biosafety certificates, the developers of *Bt* Shanyou 63 and Huahui 1 were ready to apply for plant variety rights so as to secure exclusive control in the market. In the meantime, the public sentiment toward possible and potential risk associated with the new technology also reached its peak. Although most Chinese public do not have a clear perception of GM technology, they are very cautious about the commercialization of GM rice, as in recent surveys conducted in large Chinese cities such as Beijing, Shanghai, and Wuhan have shown (Li *et al*., 2012). This, plus the concerns over the ownership of IPRs of the Chinese GM rice, may have pushed the Chinese government to reconsider and, in fact, postpone the commercialization of GM staple crops such as rice, corn, and soybeans (Stone, 2008). The uncertainties have frustrated China's GMO research community.

## 3. GM CROP PATENTING ACTIVITIES IN CHINA

Accompanying the significant investment in R&D of GM crops over the past several decades has been an explosive growth in the number of agricultural biotechnology patents in China. The number of such patent applications filed with the SIPO, China's patent office, in 2009 was a 75-fold increase over that in 1985 (Fig. 1), and by the end of 2011, the total number of domestic applications for agricultural biotechnology invention patents reached 25,643, accounting for 71.0% of the total agricultural

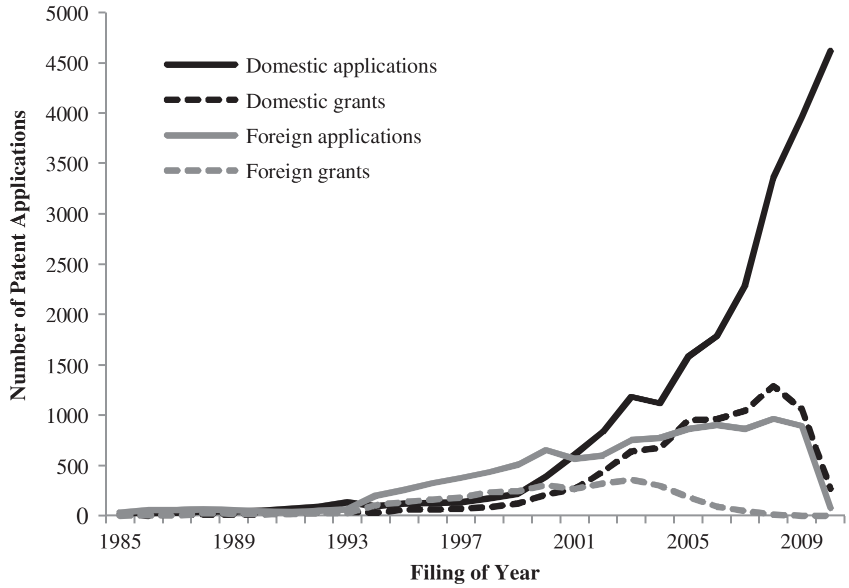


**FIG. 1.** Chinese patents on agricultural biotechnology, 1985–2009.
**Source:** Authors' search of the SIPO patent database.
**Notes:** The "declining" trends in grants and foreign application occurred after 2005 because of time lags between the filing date, publication date, and the grant of recent patents.

biotechnology invention patent applications received by the SIPO. Compared with only one or two filings in the early 1990s, the annual patent applications for GM cotton alone reached 64 in 2009. Of the granted invention patents, 72.5% have gone to universities and public research organizations. For example, of the 356 GM cotton-related patents that the SIPO has granted, 266 have been granted to the domestic public sector.

With the IPRs in place, transgenic technology started to transform Chinese farming "from high-input and extensive cultivation to high-tech and intensive cultivation" (Stone, 2008). Again, in the area of GM cotton, Chinese scientists have filed two essential patents on insecticide Crystal protein isolated from *Bt* in 1995 and 1998, which can be transformed to produce *Bt* cotton cultivars with resistance to bollworm. Now, more than 90% of transgenic cotton varieties planted in China has been developed against these two indigenous patented genes, which has made *Bt* cotton the biggest success in China.

In line with the propensity of GM rice R&D, patent applications also have increased remarkably. As of the end of 2011, Chinese domestic entities had filed 1,059 patents to protect a wide array of methods, materials, and products involved in the development of GM rice, which in fact accounts for approximately 15% of the worldwide applications. The rising number of Chinese GM rice patent applications has paralleled the worldwide trajectory in ag-biotech patenting. For example, global annual filings were no more than 100 before 1998, but the number rapidly went up to around 1,000 in 2010. The Chinese patent landscape shows public sector domination, with universities and public research organizations accounting for 87.9% of the applications (Fig. 2). Of them, the Chinese Academy of Sciences (CAS), Chinese Academy of Agricultural Sciences (CAAS), Zhejiang University, and Huazhong Agricultural University are the main Chinese applicants.

Between 1985, when the GM rice program started, and 1998, when the first field trials took place, there were quite a few patent applications. Since 2005, the number of applications has surged, indicating that the Chinese GM rice R&D has entered a fast-growing period. However, most of the Chinese applications have been filed only in China, and no more than 3% of these applications have simultaneously been filed abroad. The majority of Chinese patents claim selectable markers, detection methods, and functional genes related to GM rice. Our patent search seems to indicate that only one patent was granted on Huahui 1 and *Bt* Shanyou 63 by the SIPO, and that this patent does not have any family members in foreign patent offices. In contrast to the Chinese patenting strategy, which focuses on domestic protection, big agricultural biotechnology companies such as Monsanto, Bayer, and Syngenta have very actively

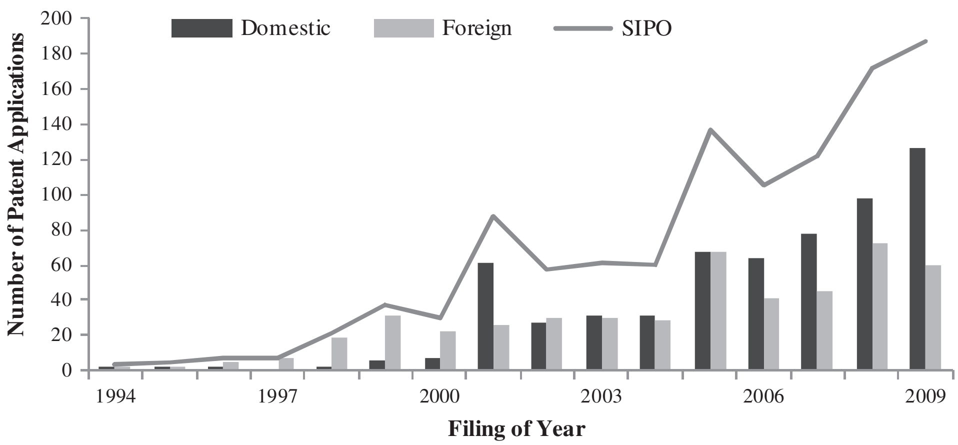


**FIG. 2.** Patent filing on GM rice in China.
**Source:** Same as Figure 1.

submitted their patent applications to the SIPO as well as patent offices of other main rice-producing and -consuming countries. For example, approximately 23% of the GM rice patent applications received by the SIPO have come from those foreign entities. Finally, although Chinese institutions of learning have filed more applications than foreign applicants, very few of their patents could cover standard transformation methods and components used in GM crop R&D. This may be one of the reasons that GM opponents such as Greenpeace have questioned whether Chinese GM rice lines are covered by foreign patents.

## 4. BACKGROUND OF *Bt* SHANYOU 63

Both Huahui 1 and *Bt* Shanyou 63 have been developed at the State Key Laboratory of Crop Genetic Improvement of the Huazhong Agricultural University in Wuhan. The laboratory is headed by Dr. Qifa Zhang, a well-known plant geneticist who is an academician of the Chinese Academy of Sciences as well as a foreign associate of the U.S. National Academy of Sciences (NAS), although Zhang himself has not been directly involved in the research. The R&D has been supported by multiple Chinese government funding sources, including that through the 863 and 973 Programs.

The research started in 1995. Four years later, Jumin Tu and Zhongming Peng, both from Zhang's group, got significant results on Huahui 1 and *Bt* Shanyou 63, which were appraised by the evaluation expert group from China's MOA.[7] The field trial soon began, and the environmental release was completed in 2002. Then the final phase—preproduction trial—was carried out between 2003 and 2004. In late November 2004, both Huahui 1 and *Bt* Shanyou 63 were submitted to the OAGEBA for biosafety certification for commercial production (Liu and Li, 2010). However, the approval process was extraordinarily time-consuming. Indeed, it took almost 10 years for both Huahui 1 and *Bt* Shanyou 63 to go through the process from the R&D completion to production approval. Then, according to China's Seed Laws, before commercial production, any varieties of major crops, including GM rice, must apply for crop variety examination, which seems to be another hurdle for the GM rice commercialization in China. To our knowledge, so far, biosafety certificates issued to *Bt* Shanyou 63 and Huahui 1 have expired.

As indicated, both *Bt* Shanyou 63 and Huahui 1 are varieties of *Bt* rice in which *Cry* genes derived from *Bt* conjugated with a suitable plant expression promoter and terminator are transformed, expressing the *Bt* toxin protein to confer resistance against insects. Both *Bt* Shanyou 63 and Huahui 1 express a *cry1Ab/cry1Ac* fusion gene, which contains a copy of the synthetic DNA sequence with two genes: the *cry1Ab* and the *cry1Ac* (Chen *et al.*, 2011). These genes encode the respective *Bt* toxins, lethal to Lepidoptera, making the plant resistant to attacks by this group of insects. Specifically, *Bt* Shanyou 63 is created to be resistant to rice stem borer and leaf roller (Tu *et al.*, 2000).

Figure 3 presents the component of one sequence of *Bt* Shanyou 63. The middle of the sequence is

[7]While Zhang was a doctoral student at that time, Tu accomplished most of his work when he visited the Philippines-based International Rice Research Institute between 1995 and 1998.

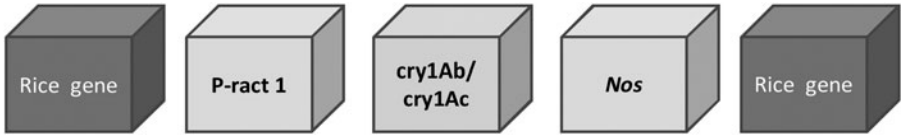


**FIG. 3.** Framework of *Bt* Shanyou 63 composition.
**Source:** Biosafety Scanner software; *available at* http://en.biosafetyscanner.org/index.php

*cry1Ab/cry1Ac*, acting as the transformed gene of interest which is resistant to lepidopteran pests. The left side contains *P-ract1*, which is the sequence of the constitutive promoter of the rice (*Oryza sativa*) actin gene. The right side is connected to the terminator, which contains the termination sequence of the nopaline synthase gene from *Agrobacterium tumefaciens T-DNA*.

In what follows, we will investigate what technology and materials have been used during the whole pipeline of GM rice R&D, which will help us better understand whether the technology and materials used in the development of the Chinese GM rice are protected by foreign patents (Fig. 4).

Two expression vectors have been found to be transformed into the receptor material of GM rice. One contains a *Bt* gene expression cassette, and the other contains a selectable marker gene expression cassette. In the vector carrying the *Bt* gene expression cassette, *cry1Ab/cry1Ac* is integrated by the highly insect-resistant active site of *cry1Ab* with the recognition site for specific insects from *cry1Ac*. The regulatory element, as described in Figure 4, is composed of the *P-ract1* promoter and nopaline synthase (*NOS*) terminator. In the vector carrying selectable marker gene expression cassette, the selectable marker is hygromycin-B-phosphotransferase (*hph*). The regulatory element

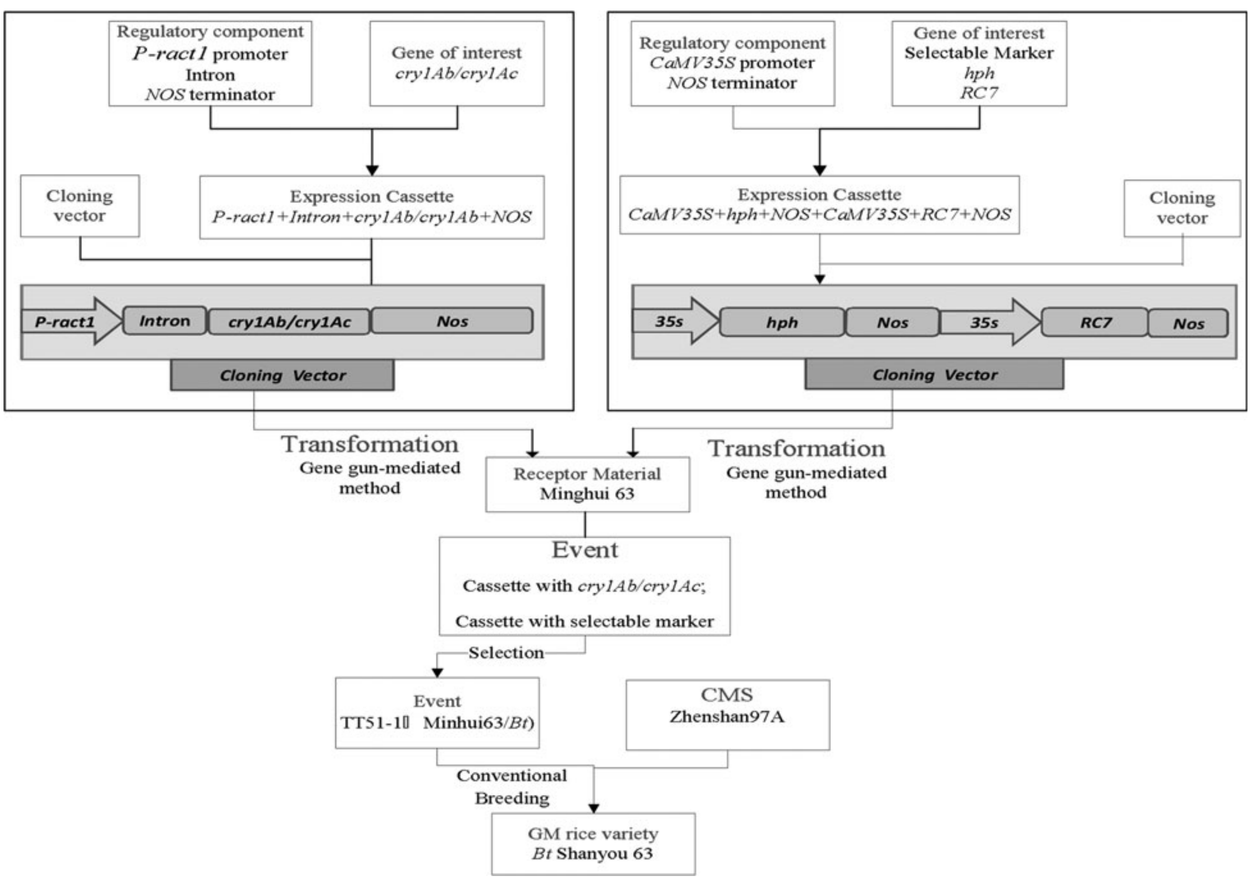


**FIG. 4.** Pipeline of Chinese GM rice R&D.
**Source:** Author's survey based on the patent document (CN200510062980.9).

consists of the cauliflower mosaic virus promoter (*CaMV35S*) and *NOS* terminator. In addition, the vector contains another expression cassette, which consists of a rice chitinase gene, *RC7*, as well as the *CAMV35S* promoter and *NOS* terminator. The two cassettes are constructed together in the same cloning vector to create an expression vector with a selectable marker.

The two expression vectors are transformed into the reception material from a conventional rice variety—Minghui 63—using the gene gun-mediated method. Then the event with the functional *Bt* gene expression cassette is kept through genetic recombination, isolation, and selection over multiple generations; and the event with the selectable marker *hph* is discarded. The target event is named TT51-1. Then, using conventional breeding methods, TT51-1 is combined with a conventional variety of rice, Zhenshan 97A. Finally, the two GM rice lines expressing *Bt* gene are generated. They are Huahui 1 and *Bt* Shanyou 63. In fact, Huahui 1 is a CMS (cytoplasmic male sterile) restorer line, and *Bt* Shanyou 63 is a hybrid of Huahui 1 and Zhenshan 97A (the CMS line). Because only one hybrid variety can be used in final production, the following discussions focus on *Bt* Shanyou 63.

## 5. PATENT PORTFOLIO ANALYSIS: DECONSTRUCTION OF THE COMPONENTS OF CHINESE GM RICE

### *5.1 Overview*

Transgenic crops embody numerous components and processes, each of which may be associated with intellectual property or technical property rights (Kowalski *et al.*, 2002). The product deconstruction of *Bt* Shanyou 63 is complex. Theoretically, three types of techniques and components are involved in its R&D, which are public domain knowledge, proprietary techniques, and technique property. Our analysis of the IP is based on the first two types of techniques, which can be found in related and relevant literature, including patents in the PTO, EPO, and SIPO patent databases, as well as other references in scientific literature databases such as the Web of Science and Chinese CNKI (a Chinese database of academic journals). A limitation of our study is that we do not have access to private information, such as trade secrets or contracts and material transfer agreements, such as those between the Huazhong Agricultural University, the developer, and related stakeholders. Therefore, the last type of techniques—technical property—such as computer software, germplasm, and biological materials and derivatives, are not available for examination. We will discuss that issue further in the conclusion.

Of the six patents that are potentially implicated in the R&D of *Bt* Shanyou 63, five—the essential components and techniques, including the promoter, transformation method, and selectable marker used in the product—are owned by foreign entities (Table 2). In particular, the *CAMV35S* promoter and gene gun-mediated methods are owned by Monsanto, the Selectable Marker *hph* by Syngenta, the *P-ract1* promoter by Cornell University, and the *RC7* gene by two Japanese public research institutes. The sixth, and the only successful event, is protected by the developer's patent in China. Additionally, although the application for plant variety protection for the restorer line of *Bt* Shanyou 63 was submitted to the Chinese MOA early in 2000 by Huazhong Agricultural University, until now, the right has not been granted.

TABLE 2. PATENTS RELATED TO *Bt* SHANYOU 63

| *Components and Methods* | *Title of Patent (Country of Filing and Number)* | *Patent Holder(s)* |
|---|---|---|
| Promoter (*CAMV35S*) | Method for enhanced expression of a DNA sequence of interest (US5424200) | Monsanto |
| Transformation method (gun-mediated method) | Method of creation transformed rice plant (US6288312) | Monsanto |
| Promoter (*P-ract1*) | Rice actin gene and promoter (US5641876) | Cornell Research Foundation |
| Selectable marker (*hph*) | Selectable marker for development of vectors and transformation systems in plants (US5668298) | Syngenta |
| Gene (*RC7*) | Complementary DNA for rice chitinase having lytic activity against molds and bacteria, and vector containing said complementary DNA and transformant (US6124126) | National Food Research Institute, Bio-oriented Technology Research Advancement Institution, Japan |
| Event (TT51-1) | Method of breeding genetically transformed rice (CN200510062980.9) | Huazhong University of Agriculture, Zhejiang University |

**Sources:** Authors' search of the PTO, EPO, and SIPO patent databases.

Table 3. Scope of Protection of Foreign Patents

| *Stage* | *R&D* | | | | *Commercialization* | |
|---|---|---|---|---|---|---|
| *Coverage* | *Amino acid* | *Nucleic acid* | *Expression cassette*[a] | *Event* | *Seed* | *Non-living organism* |
| *hph* | | | | | | Undefined |
| *RC7* | | | | | | Undefined |
| *P-ract1* | | | | | | Undefined |
| *CAMV35S* | | | | | | Undefined |
| Gene gun method | | | | | | Undefined |

**Sources:** See notes to Table 2.
Covered by foreign patents:
[a]Including expression vectors carrying the cassette.

### *5.2 Protection Scope of Foreign Patents*

In order to determine whether the Chinese GM rice is fully covered by the above-mentioned patents, we further scrutinize the scope of protection of these patents, which is defined by the claims presented in the patent document as well as the extended rights set by the national patent legislation. The interpretation of claims in patents dealing with genes and transformation process can be extremely complex, with certain patents having claims that appear to cover a wide range of living organisms.

We have carried out in-depth analysis of the scope of protection of the five foreign patents (Table 3). As *P-ract1*, CAMV35S, *hph,* and *RC7* belong to the upstream techniques, if any expression cassette, vector, event, and seed uses them without getting licenses from the patent owners, this can be considered patent infringement. Likewise, if any organism is transformed with the so-called gene gun (or gene gun-mediated method), the patent protection also covers all the events and related seeds derived from the organism. Additionally, we could not find any particular patent applications on the *NOS* terminator which has been published very early (Depicker *et al.*, 1982). If any living organism generated by *Bt* Shanyou 63 enters a country where these foreign patents are in force, it will definitely fall into the "trap" of these patents to which Greenpeace alluded. However, patent laws in most countries do not clearly define whether the patent is applied to the non-living products (*e.g.* food, feed) that use a patented component or method. To date, only the European Union rules that its patent law cannot be used to bar imports of products made from biotech ingredients that are patented in the EU, but not in the exporting country.[8] To understand thoroughly the IP risks facing commercialization of *Bt* Shanyou 63, we further investigate in which countries these patents have been filed and when they will expire.

### *5.3 Protection Period and Geographical Coverage of Foreign Patents*

Given the nature of patent rights, the protection conferred by a patent is limited to a specific term (generally 20 years from the filing date of the application) and the geographic area to which the invention is granted. We have surveyed the geographic regions where the relevant patents have been filed and summarize the expected term of these patents in Table 4. All of the five patents in question have been granted in the U.S. but not filed in China. Meanwhile, *RC7* is protected in Japan as well; the gene gun method has been widely patented at the EPO and in Australia and Japan. Of these five patents, the one on the *RC7* gene has the longest remaining term of protection, as it will not expire until October 2018.

Our patent analysis confirms some of the findings by Greenpeace. That is, the *Bt* Shanyou 63 indeed does not hold an entire patent portfolio spanning from the upstream techniques and components to final products. All the gene, promoters, markers and others used in the R&D are not developed by its developers, who simply completed the transformation and got the target event. The event has been protected by one Chinese patent granted to the developers.

However, Greenpeace has obviously exaggerated the challenges facing the *Bt* Shanyou 63. Firstly, it diverges to those literally relevant patents when breaking down the pipeline of the *Bt* rice R&D. Secondly, it does not identify whether these foreign patents had been filed or—more importantly—granted in China. For example, the reports argue that the four *Bt* gene patents held by foreign entities may

[8]Legal protection of biotechnological inventions, European Parliament and Council Directive 98/44, Art. 9.

Table 4. Remaining Term of Patent Protection in Target Regions

| *Components and Methods* | *Target Region* | *Remaining Term* 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 |
|---|---|---|---|---|---|---|---|---|---|---|
| *hph* | US | | | | Sept. 15, 2014[a] | | | | | |
| *RC7* | US, JP | | | | | | | | Oct. 25, 2018 | |
| *P-ract1* | US | | | | Jun. 23, 2014 | | | | | |
| *CAMV35S* | US | | Jun.12, 2012 | | | | | | | |
| Gene gun method | US, EPO, AU, JP | | | | | | | | Sept.10, 2018 | |

**Sources:** See Table 2.
[a]The dates indicate the expected expire time in the US.
AU = Australia, JP = Japan.

cover the Chinese *Bt* rice. Having examined these patents, we find that they protect the fusion of *cry1Ab/cry1Ac* and *cry1F*, *cry2*, and *VIP*. But these gene sequences are completely different from the gene of interest transformed in the *Bt* Shanyou 63. So the major flaw of the Greenpeace reports is that they have just identified these patents from the similar title without examining their technical details. In fact, except for the *P-ract1* and *CAMV35S*, other patents have nothing to do with the development of *Bt* Shanyou 63. By making such a blanket conclusion, whether intentionally or unintentionally, Greenpeace has confused and indeed misled the Chinese public and probably the political leadership as well.

### *5.4 Other Potential IP Risks*

If only the patent protection is taken into account, the production of the GM rice *Bt* Shanyou 63 in China appears to be exempt from foreign patents because their owners have not sought protection in China. However, in addition to patents, contracts and trade secrets are widely considered part of intellectual property; in particular, material transfer agreements are not limited to a specific geographic area. With these contracts or agreements, which are likely to exist but which are not in the public domain, the IP risks facing Chinese GM rice could be more complex, because the use of components and methods are subject to specific contractual clauses in these agreements, even though the components and methods are not patented in China. Additionally, the components used in the GM rice R&D can be defined as genetic resources, so their utilization will be regulated by the Nagoya Protocol on Access to Genetic Resources and Benefit-Sharing.[9]

Along with the implementation of the Nagoya protocol in the member countries of the Convention on Biological Diversity (CBD), of which China is a signatory, the parties that commercialize *Bt* Shanyou 63 may also face demands for benefit-sharing by the owners of relevant genetic components (*e.g.*, promoters and selectable markers). However, because proposals on mandatory disclosure of the source of genetic resources in the patent application might not have been accepted by trade-related intellectual property rights agreement (TRIPs), benefit-sharing would not be burdensome for the commercialization of *Bt* Shanyou 63 in the near future.

## 6. CONCLUSIONS AND DISCUSSIONS

Clearly, the question of who owns the intellectual property rights of Chinese GM rice is quite complex because the GM rice R&D is a long chain process including (but not limited to) many sophisticated components and methods from genes of interest, promoters, terminators, selectable makers, expression cassettes, expression vectors, and transformation methods. In the development process, the Chinese developer at Huazhong Agricultural University may have intentionally or unintentionally used others' protected proprietary technology, including patent rights, plant variety rights, trademarks, trade secrets, know-how, germplasm, and other biological materials. In deconstructing the process of development of the Chinese GM rice *Bt* Shanyou 63, we have

[9]This international agreement aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and technologies. It was adopted by the Conference of the Parties to the Convention on Biological Diversity at its tenth meeting on 29 October 2010 in Nagoya, Japan. The Nagoya Protocol will enter into force 90 days after the date of deposit of the fiftieth instrument of ratification. *Available at* http://www.cbd.int/abs/ (accessed 10 September 2014).

reviewed reception materials, gene constructs of cloning vectors, transformation, plant regeneration, and other related techniques.

Our analysis indicates that R&D of *Bt* Shanyou 63 is potentially covered by approximately five foreign-patented components and technology, which is, however, fewer than the Greenpeace estimate of a dozen foreign patents. Furthermore, it must be clearly stated that because all of these foreign patents have not earned protection in China until now, if there is no relevant material transfer agreements or other contracts signed between the Chinese developer and the foreign patent owners, there will not be any IP risks associated with the commercial activities in China. Therefore, Greenpeace's argument is not valid, and Chinese farmers do not have to pay royalties to foreign companies and organizations for growing the *Bt* rice on Chinese land.

However, it is premature to conclude that there would be no challenges facing China in commercialization of GM rice in the international market. Particularly if the seeds or other living organism generated from the *Bt* Shanyou 63 flow into the U.S., EU, Japan, or Australia between now and 2018, while some of the above-described technologies are under patent protection in these countries, the Chinese developer could be sued by the relevant patent holders. Moreover, given that no clear legal and internationally accepted rules on whether non-living products are subject to biotechnological patent protection, the trade on food and feedstuff produced by the Chinese GM rice may also face lawsuits in these countries.

While the research covers only *Bt* Shanyou 63, its finding should not be limited to GM rice and can have implications for other GM crops developed in China. In retrospect, the case of *Bt* cotton in China may have taught a lesson. *Bt* cotton is the biggest success of the Chinese agricultural biotechnology program. It started to be commercialized in China in 1997 and has accounted for more than 90% of cotton planted in northern China since 2004 (Wu *et al*., 2008). On the one hand, the Chinese *Bt* cotton has faced the similar international patenting landscape as the *Bt* rice has. Foreign companies such as Monsanto have not patented their *Bt* genes in China, although they own patents on these genes that are important in the production of the cotton, including that developed by Chinese. Therefore, *Bt* cotton commercialization can have been done without the risk of patent infringement, at least in the domestic market. The *Bt* cotton example could free the Chinese government and developers from concerns about the potential patent lawsuits. As such, the government and especially the ambitious developers can confidently distribute *Bt* rice on a large scale and will not be challenged on the patent front.

On the other hand, the developers of Chinese *Bt* cotton have established a more rigorous and efficient IP protection framework than their *Bt* rice counterparts. For example, the *Bt* genes inserted into all of the China-produced *Bt* cotton varieties have been patented in China by the Biotechnology Research Institute of CAAS. A transformation process for inserting genes—the pollen tube pathway system—was developed by Chinese scientists (Hu *et al*., 2009; Pray *et al*., 2001), and most of the *Bt* cotton varieties have been covered by plant variety rights. By contrast, the *Bt* Shanyou 63 was not granted with plant variety rights for almost 14 years after application, and the biosafety certificate has lapsed in August 2014. Thus, if it is commercialized in the domestic market, the developer and seed companies cannot be guaranteed significant economic benefits similar to those of *Bt* cotton; the market incentives for Chinese seed firms to commercialize *Bt* rice may therefore be insufficient.

All in all, from a practical perspective, the lessons from both *Bt* cotton and *Bt* rice should push the Chinese government and the GM crop developers to establish a dynamic IP risk management strategy. These lessons in turn should enable Chinese developers to refine their R&D strategy. In order to avoid infringement, they need to perform IP analysis *before* starting research rather than at the stage of commercialization, which is too late. Meanwhile, they must take preemptive measures to protect their innovation.

As mentioned, our intellectual property analysis of the *Bt* Shanyou 63 relies only on the patent documents and scientific literature. The information on nucleic acid and amino acid sequences of the GM rice components disclosed in some patents is not complete, and the details of technique properties, such as material transfer agreements, are not available for examination. Had we had such information, we would have further examined its impact on the commercialization of the Chinese GM rice.

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