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Innovation in Biotechnology Seeds: Public and Private Initiatives in India and China

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ABSTRACT

This paper compares and contrasts how innovation—the successful introduction of new products, services, or techniques—is occurring in biotechnology seeds in China and India. We begin with an overview of the agricultural challenges faced by China and India and the substantial investments that both countries are making in agricultural research and development (R&D) and biotechnology to address these challenges. We next describe each country's approach to three factors identified by industry as important to innovation in biotech seeds: market access, intellectual property (IP) protection, and efficient regulatory review processes. We find substantial problems in all three areas including limited market access for foreign firms in China and significant price caps in India; limitations and gaps in IP protection and enforcement; and lengthy delays in regulatory review. We conclude with a case study highlighting how the three factors shaped the introduction and adoption of the first widely commercialized biotech crop in China and India, Bt cotton.

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Introduction

This paper compares and contrasts how innovation—the successful introduction of new products, services, or techniques—is occurring in biotechnology seeds in China and India. We begin with an overview of the agricultural challenges faced by China and India and the substantial investments that both countries are making in agricultural research and development (R&D) and biotechnology to address these challenges. We next describe each country's approach to three factors identified by industry sources as important to innovation in biotech seeds: market access, intellectual property (IP) protection, and regulatory review processes. In considering these three factors, we find a number of problem areas:

- **Market access**: China significantly limits the market access of foreign firms, while India has liberalized its seed sector and permits foreign and domestic firms to participate on equal terms. However, price restrictions implemented by Indian state governments severely limit the ability of all firms to charge market prices for biotech seeds.

- **IP protection**: Both countries have patent and plant variety protection laws that provide some protection for new plant technologies, although with limitations that discourage private sector activities. Foreign firms are active in seeking patent protections in both countries, but domestic firms are not. The public sector is an important user of IP protection systems, particularly in China.

- **Regulatory review**: Biotech seeds sponsored by the public and private sectors have languished for long periods in the review pipeline. Both countries consider factors unrelated to biosafety in determining whether to approve new biotech seeds, a practice that causes delays and undermines the predictability of the regulatory process. In addition, both countries have difficulties with the enforcement of IP and regulatory laws. The sale and use of illegal seeds—those that violate IP laws or those that have not undergone regulatory review—is an ongoing and substantial problem in India and China.

We conclude with a case study highlighting how these three critical factors shaped the introduction and adoption of the first widely commercialized biotech crop in China and India, Bt cotton.[2]

Agricultural Challenges in China and India

India and China have achieved remarkable economic growth over the last decade, although growth in the agricultural sector has lagged behind growth in the general economy.[3] In both countries, the agricultural sector faces the tremendous challenge of producing more with fewer resources. According to the United Nations (2009), global food production must double by 2050 to meet the needs of the world's growing population. Diminishing arable land and water per capita, climate change, plant diseases and pests, pollution, and ecosystems depleted by the application of fertilizers and pesticides present substantial additional challenges (Tuli et al. 2009, 319). To address these challenges, the Chinese and Indian governments have made investing in agricultural R&D, and particularly in agricultural biotechnology, a priority.

Biotechnology is broadly defined as the use of the biological processes of microbes and plant and animal cells for the benefit of humans (USDA, ERS 2009a). Agricultural biotechnology provides a more sophisticated and precise means of modifying plant genetics than that practiced by plant breeders for centuries through breeding and crossbreeding. Instead of transferring thousands of genes using traditional methods, biotechnology enables breeders to transfer only selected genes. Moreover, by expanding the possible universe of transferable genes to include essentially any living organism, biotechnology enables the introduction of beneficial traits that would be difficult or impossible to create through traditional breeding methods (Giddings and Chassy 2009).

The first-generation of biotech crops include those that have been genetically engineered to improve resistance to insects and tolerance to herbicides,

[2] Bt cotton is a genetically modified crop that includes a gene from the soil bacterium *Bacillus thuringiensis*. The bacterium produces a protein that is toxic to certain lepidopteran insects, particularly the bollworm. Cotton containing the Bt gene is able to produce the toxin, making the plant insect resistant (USDA, ERS 2009a).

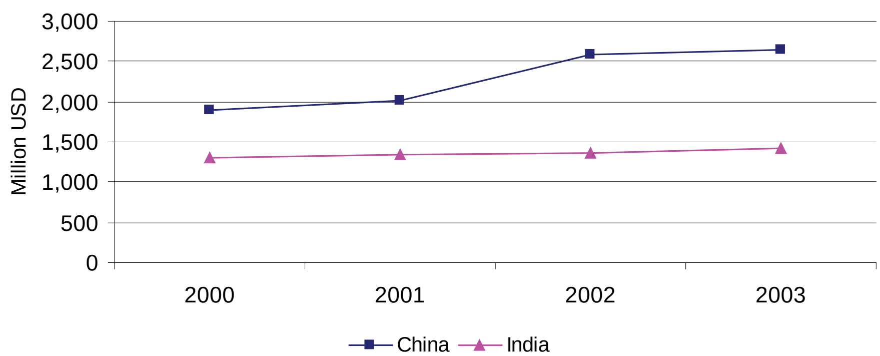
[3] Since 2000, India has experienced average real GDP gains of about 7 percent, and China of almost 10 percent (IMF 2009). In Indian agriculture, however, annual GDP growth rates declined to 2.5 percent during the period 1997–2007 (compared to 3.7 percent in the previous five-year period) (Government of India, Ministry of Finance 2008). By contrast, in China agricultural output grew about 7 percent per year during the period 1997–2007 (USDA, ERS 2009b).

thus enabling farmers to use less pesticide and obtain higher yields. Genetic engineering to increase a plant's tolerance to drought or to high salinity levels, or to improve the nutritional content of crops, are promising emerging areas of agricultural biotechnology (CEI 2008, 13).

Government Investments in Agricultural Biotechnology

Increased agricultural productivity depends on R&D to support innovation. China and India have made significant investments in this area; they rank third and fourth, respectively, in public sector agricultural R&D spending, behind the United States and Japan. In 2000, the United States invested the equivalent of about $4.4 billion in agricultural R&D, compared to $2.5 billion for Japan, $1.9 billion for China, and $1.3 billion for India (Beintema et al. 2008, 1). Since 2000, agricultural R&D spending has grown much more rapidly in China, reaching $2.6 billion in 2003. By contrast, as figure 1 shows, public sector R&D spending in India remained relatively unchanged during the period.

FIGURE 1 China and India total public sector agricultural R&D spending (million, PPP $), 2000-03



Source: ASTI database.

Within the general field of agricultural R&D, China and India have identified biotechnology as a critical tool for overcoming the significant challenges to increasing productivity. According to an official in India's agricultural R&D program, "The search, characterization, isolation and utilization of new genes through application of biotechnology are essential for the revitalization of Indian agriculture" (Rai 2006). During the years 2002–06, the Indian Ministry of Science and Technology's Department of Biotechnology (DBT) implemented 481 agricultural biotechnology programs. Going forward, the

DBT has identified as R&D priorities the development of biotech crops that are disease and pest resistant, drought and salinity tolerant, and nutritionally enhanced (Government of India, Ministry of Science and Technology 2006, 8, 180).[4] There are few published estimates of India's total R&D expenditures on agricultural biotechnology across relevant agencies. One exception is James (2008, 60) who estimates that India's public sector investments in crop biotechnology R&D have been approximately $1.5 billion over the last five years, or $300 million per year.

Like India, China has promoted biotechnology as an important tool for boosting agricultural productivity, food security, and rural incomes. Agricultural biotechnology R&D programs are overwhelmingly financed and implemented by China's public sector. As of 2001, there were more than 150 national and local laboratories in more than 50 research institutes and universities working on agricultural biotechnology, under the direction of the Ministry of Science and Technology (MOST) and the Ministry of Agriculture.[5] One important public funding programs for agricultural biotechnology is the National High Technology Research and Development Program (known as the 863 program). Agricultural biotechnology funding under the 863 program has grown significantly, from $4.2 million when the program began in 1986 to $55.9 million in 2003 (Huang et al. 2004, 3, 7).

In recent years, China has elevated the status of agricultural biotechnology and stressed the importance of developing domestic IP in the field. As Chinese Premier Wen Jiabao stated in 2008, "To solve the food problem, we have to rely on big science and technology measures, rely on biotechnology, rely on GM [genetic modification]" (James 2008, 93). In July of 2008, the State Council approved a budget increase for government funds allocated to genetically modified crops of $584–$730 million per year. The aims of this new initiative reportedly are for China to "obtain genes with great potential commercial value whose intellectual property rights belong to China, and to develop high quality, high yield, and pest resistant genetically modified new species" (James 2008, 93; Shuping 2008). Government policies in the IP area have had a significant impact on the course of innovation in agricultural biotechnology in China and India, as set forth below.

[4] Other Indian public sector institutions substantially involved in agricultural biotechnology R&D include the Indian Council of Agricultural Research (ICAR) and the state agricultural universities (SAUs) (Beintema et al. 2008, 2).

[5] More recently, MOA has taken over from MOST the management of central government funds directed to agricultural biotechnology R&D (Petry and Rohm, 2009, 2).

Government Policies Affecting Agricultural Biotechnology

Industry sources have identified government policies in three areas as important to successful innovation in agricultural biotechnology in India and China: market access conditions; the availability of IP protections; and the speed and manner in which regulatory systems review new biotech products. In this section we will outline how the two countries stand with regard to these factors.

Private Sector Access to Seed Markets in India and China

Until recently, seeds have predominantly been a public sector business in both India and China. And while this is still the case in China, in India the situation has changed dramatically. Until the late 1980s, private firm participation in the seed industry in India was limited by two factors: economy-wide policies that restricted foreign investment and licensing, and seed-specific policies that limited the sector to "small scale" participants and severely restricted imports of research or breeder seeds. With India's implementation of the Seed Policy of 1988, the "small scale" limitation was removed, large domestic and foreign firms were permitted entry, and import restrictions were substantially lifted. Economy-wide liberalization occurred in India in 1991, including the abolition of the industrial licensing system and the easing of restrictions on foreign direct investment (FDI) (Pray, Ramaswami, and Kelley 2001, 589).

These reforms effectively opened the market to private participation. Pray, Ramaswami, and Kelley (2001) found that as a result of the reforms, new foreign and domestic firms entered the market, competition increased, and private sector R&D expenditures grew rapidly as domestic firms spent more on technology to compete with the entry of new research-intensive foreign firms. Another important motivation for firms' increased R&D expenditures has been the market's transition away from open-pollinated varieties (OPVs), which farmers can save and reuse in subsequent years, to hybrids, which cannot be reused without a significant reduction in yield and quality. Farmers' need to purchase seeds each year enables firms to recoup R&D investments (Pray, Ramaswami, and Kelley 2001, 596–97).

U.S. and other global seed companies with a substantial presence in the Indian hybrid and biotech seed markets include Monsanto (United States), Bayer CropScience (Germany), DuPont/Pioneer (United States), Syngenta (Switzerland), and Dow AgroScience (United States). Leading Indian firms include Rasi Seeds, the Maharashtra Hybrid Seed Company (Mahyco), Nuziveedu Seeds, and JK Agri-Genetics (Bayer CropScience 2006). The agricultural biotechnology sector in India reportedly had total revenues of about $318 million in 2008, an increase of 353 percent in the last five years (BioSpectrum 2009).

The Indian seed market is competitive. Murugkar, Ramaswami, and Shelar (2007) found that the cotton seed market, which accounts for about one fourth of the overall seed market, has low levels of market concentration, a diverse group of foreign and domestic firms of various sizes, and market leadership that fluctuates over time and across Indian states. Nonetheless, they noted two factors that detracted from healthy competition: state-level price caps placed on biotech cotton seeds, and a substantial market in illegal seeds.[6]

The state government of Andhra Pradesh was the first to implement price restrictions. Its 2006 directive capped prices for biotech cotton seeds at less than one-half the prevailing market price. Today, price caps have spread to important cotton-growing states throughout the country including Maharashtra, Gujarat, Tamil Nadu, Karnataka, Madhya Pradesh, and West Bengal (Mishra 2006). The U.S.-India Business Council (2009, 6) identifies non-market-based pricing as one of the most significant disincentives to the commercialization of new biotech seeds by global seed firms in India. According to the founder of Rasi Seeds, continued state government interference in pricing also is harming the ability of indigenous companies to develop and commercialize biotech seeds (Suresh and Rao 2009, 299). Price caps have been found particularly problematic for new domestic firms seeking to enter the market (Murugkar, Ramaswami, and Shelar 2007, 19–21).

Even with significant price controls, however, India's seed market is more liberalized than that of China. Despite the enactment of a seed law in 2000 creating a role for private firms, China continues to severely restrict FDI and the trading of certain types of seeds (USCIB 2009, 32–33). Moreover, due to the historic role of state planning, Chinese seed markets are fragmented by geography and function. Historically, each province or prefecture had its own seed company, which generally had monopoly rights within its geographic domain. Although the 2000 seed law is intended to facilitate the marketing of seeds across geographic areas, local markets remain difficult for nonlocal firms to access, according to field research conducted by Keeley (2003, 33–

[6] Illegal seeds are discussed in the regulatory review section of the paper.

34). Fragmentation across functions is also the norm: few firms are vertically integrated across the R&D, breeding, production, sales, and marketing functions (Sanchez and Lei 2009, 5).

FDI restrictions are severe and, not coincidentally, arose at the same time that Monsanto began to successfully market its biotech cotton seed in China. In 1997, the year Monsanto's product was first approved, a new seed regulation required that any foreign company wishing to produce and sell cotton and other seeds had to enter into a partnership in which the Chinese partner maintained the controlling interest; invest prescribed amounts of capital; and obtain central government permission (Reddinger 1997, 1). This new regulation required Monsanto to reduce its initial controlling interest in its cotton joint venture, reportedly so that the Chinese partners could obtain more economic benefits from the partnership (Keeley 2003, 33).

FDI laws became even more restrictive in 2002 when China's Foreign Investment Guidance Catalogue prohibited any new foreign investment in the development and production of genetically engineered planting seeds (Gifford, Qing, and Branson 2002, 3). These prohibitions are maintained in the most recent FDI catalogue issued in 2007. Moreover, although foreign firms may invest in the development, breeding, and production of new varieties of conventional seeds, their investment must be limited to minority shareholder status in joint ventures with Chinese partners (Petry 2007, 2).

These FDI restrictions reportedly arose out of Chinese government concerns about food security and the competitiveness of its domestic industry in light of the commercial success that Monsanto experienced with its biotech cotton product (Thomas 2007, 55–56). Concerns about multinational companies dominating the seed industry persist today. The Chinese Academy of Science and Technology for Development (CASTED), for example, recently stated that the seed industry is a strategic one and that the opening up of the industry threatens the survival of domestic firms and the security of China's germplasm resources (CASTED 2009).

Notwithstanding the market access restrictions, foreign firms have been permitted to undertake several new biotech R&D projects in China. New investments reportedly are permitted if they are limited to research and experimentation, and do not extend to the commercialization of new products.[7]

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[7] Industry representative, e-mail message to Commission staff, August 18, 2009.

Syngenta, for example, is building a research center in Beijing for the early evaluation of genetically modified traits in key crops, and has a number of ongoing collaborations with Chinese research universities (Syngenta 2008). Bayer CropScience has entered into a memorandum of understanding with the Chinese Academy of Agricultural Science (CAAS) for the "joint development and global marketing of new agricultural products" using the latest plant breeding and biotechnology processes (Bayer CropScience 2008). Although FDI restrictions remain in place, foreign firms appear to have concluded that the R&D they do in China today ultimately will lead to products they can commercialize there in the future. [8]

The Importance of IP Protection

IP protection for biotech seeds is an important framework condition for innovation, because the development and commercialization of new products involves large research expenditures, uncertain outcomes, and lengthy and costly regulatory procedures (Maskus 2004, 721). Monsanto, for example, estimates R&D investments for new biotech corn products at $5–10 million for the proof-of-concept phase and $10-15 million for early product development (Monsanto India Ltd. 2009, 7). Kalaitzandonakes, Alston, and Bradford (2007, 510) found that to obtain regulatory approval, global seed firms incurred compliance costs ranging from $7 million to $15 million for herbicide-tolerant and insect-resistant corn submitted to regulators in 10 countries. The initial innovating firms cannot obtain a return on their heavy R&D and regulatory compliance costs if competitors are permitted to free-ride on their work.

An additional challenge arises from the "natural appropriation problem" of seeds (Maskus 2004, 722). OPVs can be reproduced simply by cultivating and reusing them, and biotech seeds can be relatively easily copied by competitors employing the latest biotechnology techniques. By contrast, hybrid seeds have some built-in protection mechanisms: they lose their superior yield potential and other valuable characteristics in subsequent plantings, thus reducing the motivation of farmers to save seed. Moreover, commercial competitors cannot reproduce hybrid seeds without access to the parental lines used to develop them; keeping those lines physically secure reduces the appropriation problem (World Bank 2006, 7–8). However, even these built-in protections have their

[8] Other observers are less sanguine, emphasizing the substantial (and strategic) uncertainty that is created by China's approval of particular projects while severely restrictive FDI regulations remain in place. Industry representative, telephone interview by Commission staff, November 23, 2009.

limitations. Seed production in India and China tends to be concentrated in geographic zones with favorable agronomic conditions; the presence of many competing firms working in a relatively small area creates numerous opportunities for misappropriation (Tripp, Louwaars, and Eaton 2007, 360).

As WTO members, China and India must make IP protection available for seed-related inventions. The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires that member countries make patents available for inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness, and industrial applicability (TRIPS, art. 27.1). Although there is an exception to this general rule of patentability for plants and animals, it is limited: members must still allow inventors to patent microorganisms and microbiological and non-biological processes for the production of plants and animals. It is left to each member's legislators, courts, and patent offices, however, to define critical terms and to determine if a particular biotechnology product or process is novel, inventive, and has an industrial application.

Moreover, if a member country does not provide patents for plant varieties, it must provide an effective alternative system (TRIPS, art. 27.3(b)). Some countries, including the United States, offer both patents and an alternative system to protect plants. Most developing countries, including India and China, provide only an alternative system, using the model supplied by the International Union for the Protection of New Varieties of Plants (UPOV).

Patents in India and China

Both India and China exclude plants and seeds from patent protection but provide some patent protection for microorganisms and for non-biological and microbiological processes used to produce plants. However, global seed firms have expressed concern about the actual scope of the coverage given to biotechnology products and processes in both countries. Global firms also have expressed concern about the requirement in both countries that patent applications identify the source and geographic origin of biological materials used to make an invention, stating that it is ambiguous and burdensome. Patent law provisions in both countries that permit compulsory licensing under a wide variety of circumstances also give rise to significant industry concerns.[9]

India and China have granted some agricultural biotechnology patents. According to online records of the Indian Patent Office, Monsanto holds the largest number of recently granted patents for seed technologies.[10] For example, it has obtained a patent for "Cotton Event Mon15985," the genetics underlying the second generation of its biotech cotton seed product, as well as patents for biotechnology processes used in producing plants with herbicide tolerance, improved germination rates, and other valuable traits. Biotechnology patents for improved traits for rice, cotton, corn, and other crops, as well as biotechnology-based seed coatings and treatments, have been issued to Bayer and Syngenta. Global seed firms also have a substantial number of biotechnology patent applications pending. [11]

By contrast, most large Indian seed companies, such as Rasi Seeds and Nuziveedu, do not hold patents or pending applications for seed-related technologies. One exception is Mahyco, which has a number of seed biotech applications pending. Public sector research institutions, such as ICAR and the Council for Scientific and Industrial Research (CSIR), also hold few seed biotech patents or applications at the Indian patent office. [12]

In China, there is substantial patenting of seed biotechnologies by foreign firms (figure 2).[13] Monsanto has the largest number of granted patents and pending applications. For example, it has obtained patents related to its insect-resistant

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[9] See BIO 2009, 2-3; industry representatives, e-mail message to Commission staff, June 19 and August 18, 2009; industry representatives, telephone interviews by Commission staff, August 10, 2009 and November 23, 2009; and industry representative, interview by Commission staff, Beijing, October 23, 2009.

[10] The Controller General of Patents, Designs, and Trademarks (Indian Patent Office) has online search facilities that permit the searching by applicant name of "new records" of granted patents. See Indian Patent Office, Public Search for Patents, *http://ipindia.nic.in/pat-sea.htm* (accessed July 12, 2009). Although date parameters for new records are not provided, they appear to comprise patents granted since 2007.

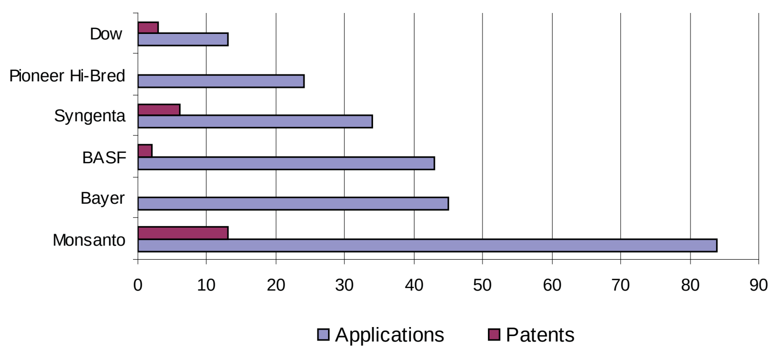
[11] India Big Patents Web site, *http://india.bigpatents.org* (accessed July 20, 2009).

[12] CSIR patents in the fields of agriculture and biological sciences can be accessed on its patent database, *http://www.patestate.com/* (accessed September 8, 2009). See also India Big Patents Web site, *http://india.bigpatents.org* (accessed July 20, 2009).

[13] Agricultural biotechnology patents were identified by reviewing patents issued and applications made by the leading global seed firms, using the following search terms—"seed," "plant," "bacillus," "corn," "rice," "cotton," or "transgenic"—on the China patent database, *http://search.cnpat.com.cn* (accessed August 15, 2009).

cotton and for genetic sequences in corn, bentgrass, and soybeans that confer tolerance to herbicides, improved trait qualities, and other benefits. Other global seed firms have only a handful of granted patents in China and a larger numbers of applications pending. These pending applications are in areas such as climactic stress tolerance, yield improvement, herbicide tolerance, insect and virus resistance, and other valuable traits.

FIGURE 2 China: Global Firms' Seed Biotech Patents and Applications, 1984–2009

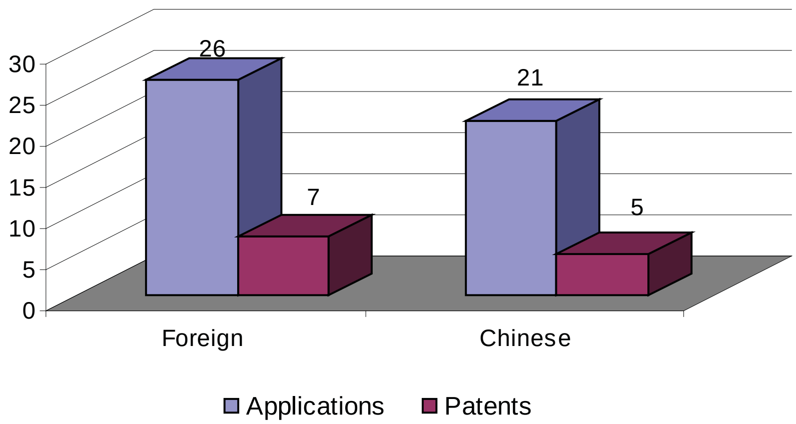


Source: China Patent Database: http://search.cnpat.com.cn.

Unlike in India, China's government-supported research institutions and universities are also important players in biotech seed patents. For example, a review of patents and applications related to Bt cotton shows substantial activity by Chinese research institutes and universities (figure 3). The research institutes of CAAS, including the Biotechnology Research Institute (BRI), all hold multiple patents or applications for Bt-related technologies, as do Huazhong Agricultural University and Central-China Agricultural University.[14] By contrast, few domestic Chinese firms hold patents or applications in the Bt technology area. China and India are thus similar in limited patenting activities by domestic companies compared with strong patenting by global firms. They differ in that Chinese research institutions and universities do engage in substantial patenting.

[14] The BRI reportedly generated about 15 percent of its income through patents in 2006 and expected to increase that share significantly going forward (World Bank 2006, 38). As will be seen in the case study, China's public sector actors have licensed Bt cotton technologies to firms that market and distribute the seeds.

FIGURE 3 China: Bt-Related Patents and Applications, 1985–2009



Source: China Patent Database: http://search.cnpat.com.cn.

Plant Variety Protection in India and China

China and India have enacted plant variety protection (PVP) laws as an alternative to offering patent protection for plant varieties. These laws provide marketing rights to developers of new plant varieties that are distinct, uniform, and stable.[15] China enacted its Plant Variety Protection Act (PVPA) in 1997 and began accepting applications to register new varieties in 1999.[16] India enacted legislation—the Protection of Plant Varieties and Farmers' Rights Act, 2001 (PPV&FR law)—in 2001, but did not begin accepting applications for the protection of plant varieties until May 2007. [17]

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[15] A variety is "distinct" if it is clearly distinguishable from another variety; "uniform" if it has relevant characteristics that can be defined for the purpose of protection; and "stable" if its relevant characteristics remain unchanged after repeated propagation. Together, these are known as the DUS criteria. UPOV Web Site. *http://www.upov.int/en/about/upov_system.htm#P177_18977* (accessed September 23, 2009).

[16] China, Ministry of Agriculture, Office for the Protection of New Varieties of Plants Web site. *http://www.cnpvp.cn/en/index.html* (accessed September 8, 2009).

[17] Government of India, Protection of Plant Varieties and Farmers' Rights Authority Web site. *http://www.plantauthority.gov.in/index.htm* (accessed September 8, 2009).

Major differences between PVP laws in India, China, and the United States are highlighted below. Plant variety rights have significant limitations and are generally considered weaker than patent rights (table 1).[18]

India provides the shortest term of protection for plant varieties, followed by China and then the United States. China and India are phasing in coverage of the law to include new crops each year; however, because India's law is of recent vintage and its application was delayed several years, relatively few crops are covered. China did not include cotton on the list of crops entitled to PVP until 2005—a delay labeled "strategic" by Keeley (2003, 23), as it appears to have been intended to enable the unrestricted spread of the first generation of biotech cotton technologies.

The most significant difference between PVP laws in the three countries is in the breadth of farmers' privileges. Under India's law, farmers are permitted to save, use, sow, exchange, share, and even sell protected seed. The only limitation is a prohibition on the sale of "branded seed." China's law permits farmers to save and informally exchange seed, but prohibits commercial sales. U.S. law is significantly more restrictive; farmers can save seed only under specific conditions, and a new variety cannot be "essentially derived" from a protected variety without sharing the benefits with the source variety's owner. Global seed firms state that the broad farmers' privileges and breeders' exemptions render PVP laws of limited commercial value in both India and China. [19]

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[18] UPOV was established in 1961 with the International Convention for the Protection of Plant Varieties (the UPOV Convention). The UPOV Convention has undergone several revisions since its enactment in 1961. The United States follows the latest revision, the 1991 UPOV Convention, which is the most protective of the rights of plant breeders. China follows an earlier version, the 1978 UPOV Convention. India's PPV&FR law, while loosely based on the 1978 UPOV Convention, contains broader exceptions intended to protect farmers. India's application to join UPOV has not been approved to date, reportedly because of deviations from the 1978 UPOV Convention. Government official, interview by Commission staff, Alexandria, VA, July 20, 2009.

[19] Industry representative, e-mail messages to Commission staff, June 19, 2009, and August 18, 2009; U.S. government official, telephone interview by Commission staff, July 24, 2009.

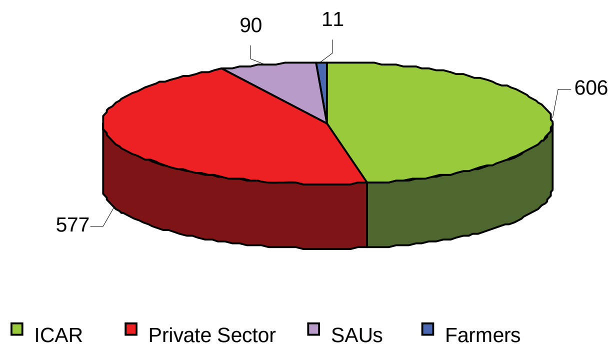
TABLE 1 Major differences in PVP laws in India, China, and the United States

	India	China	United States
Length of protection	18 years for trees and vines; 15 years for other crops and extant varieties.	20 years for vines, fruits, and ornamentals; 15 years for all other crops.	25 years for trees and vines, 20 years for other crops.
Coverage	18 crops currently eligible.	73 crops currently eligible.	No crops excluded.
Farmer seed saving and exchange	Seed saving, exchange, and sale by farmers are broadly permitted. Farmers are only prohibited from selling "branded seed."	Farmer seed saving and exchange are permitted, if noncommercial.	Seed saving and sole use by the farmer to produce a crop are permitted, subject to the legitimate interests of the breeder. Farmers cannot sell or share seed without the permission of the breeder and payment of royalties.
Breeder's exemption	Protected varieties may be used for breeding.	Protected varieties may be used for breeding.	Breeding activities permitted provided that the benefits of new varieties that are "essentially derived" from protected varieties are shared.

Sources: Indian Protection of Plant Varieties and Farmers' Rights Act (2001); U.S. Plant Variety Protection Act, 7 U.S.C. §§ 2321–2582 (2007); Regulations of the People's Republic of China on the Protection of New Varieties of Plants (1999); and World Bank 2006, 7.

Perhaps because of this limited value, the dominant users of the PVP systems in India and China are public research institutions and universities, generally seeking protection for conventional hybrids and OPVs rather than biotech plants. In India, most applications have been filed by ICAR (figure 4). The combined share of ICAR and the state agricultural universities (SAUs) equals 54 percent of all applications. Most of the remaining applications are filed by the private sector, which includes both domestic and foreign firms; few applications are filed by farmers.

FIGURE 4 Plant variety protection applications filed in India, 2007–present



Source: Indian PPV&FR Authority.

Similarly, according to data compiled in China by Hu and others (2006), 66 percent of PVP applications were filed by government research institutes during the period 1999–2004. This figure actually understates public sector involvement, as approximately half of the applications filed by the private sector were for plants developed by the public research institutions and then licensed to private firms for purposes of the application (Hu et al. 2006, 261, 264). Public sector efforts to protect and commercialize IP are not surprising, given that government research institutes in China often are expected to generate a significant portion of their own budgets. Some provincial governments motivate researchers to develop new varieties for commercialization by awarding bonuses or other privileges based on the number of applications filed (Hu et al. 2006, 265).

The public sector dominance of the PVP system in India and China stands in stark contrast to the situation in the United States, where private firms account for 75 percent of PVP filings, universities and the government only 15 percent, and foreign applicants the remainder (Strachan 2006, 2). The PVP systems in China and India stimulate some private sector R&D of new varieties but also—even more importantly, based on user statistics—motivate public sector participation.

Regulatory Review

Biotech seeds cannot be marketed until they have been reviewed and approved for release by the regulatory system. The goals of the Chinese and Indian regulatory systems are wide-ranging. In China, they are to promote biotechnology R&D, tighten the safety controls on genetic engineering work, guarantee public health, prevent environmental pollution, and maintain ecological balance. In India, they are to ensure that biotech crops pose no major risk to food safety, environmental safety, or agricultural production, and that they will not harm farmers economically. The Indian goal of protecting farmers generally is not part of the regulatory framework in developed countries (Pray et al. 2006, 142–43).

Like the United States, India and China have detailed regulatory frameworks for the review of biotech seeds, encompassing multiple agencies and numerous stages. In China, for example, these stages are intended to take place over a number of years and include laboratory development (variable, 2–4 years), contained field trials (1–2 years), environmental release trials (2–4 years), and pre-production trials (1+ years), followed by the approval or rejection of the product for commercial release (Karplus and Deng 2008, 116; Monsanto 2009, 7). In addition to biosafety review, separate procedures also exist at the state and provincial level for the registration of biotech seeds before they can be marketed. These procedures can add another 2–3 years to the time to market in China (Petry and Bugang 2008, 8).[20]

High costs and lengthy procedures can result in products being withdrawn from consideration if the costs of compliance outweigh the benefits the firm can obtain in a particular market. Bayer CropScience, for example, reportedly withdrew its biotech mustard seed from regulatory consideration in India in 2003 after approximately nine years of review and millions of dollars in costs. Bayer reported that the continued costs, uncertainty about whether the product would ever be approved, and potentially small market size all contributed to

[20] By contrast, regulatory compliance procedures take less time in the United States. Jaffe (2006, 748) calculated the time elapsing from the official submission of a regulatory package for a biotech crop to the final agency decision allowing the product to be commercialized. The U.S. Department of Agriculture (USDA), which is responsible for assessing the environmental safety of biotech crops and oversees field testing and trials, took on average 8.6 months to issue a final decision during the period 1994–2005. However, the actions of U.S. regulators have been overturned by the courts when they act too hastily and approve biotech seeds for release, for example, without the preparation of an environmental impact statement. See for example Geerston Seed Farms v. Johanns, 570 F.3d 1130 (9th Cir. 2009).

the decision not to continue with commercialization of the product in India (Pray, Bengali, and Ramaswami 2005, 273). Moreover, lengthy regulatory proceedings can have the unintended effect of encouraging the growth of illegal seed markets to fill unmet demand during protracted review periods, as occurred in India when illegal versions of Bt cotton reached the market while the legitimate product was still under review (box 1).

Both the public and the private sectors in India and China have been conducting field trials of new biotechnology crops since the late 1990s. However, no new biotech crops have been approved in India since Bt cotton in 2002. Table 2 identifies crops undergoing field trials in India. In China, Bt cotton, approved in 1996, is the only widely planted biotech crop. According to reports, stress-tolerant rice, disease-resistant cotton, insect-resistant corn, herbicide-tolerant soybeans, virus-resistant wheat, improved potato, insect-resistant poplar trees, and many other crops have undergone or completed trials and testing since 1996 (Karplus and Deng 2008, 104). Significant developments occurred in November 2009 when China's Ministry of Agriculture announced that it had issued biosafety certificates to domestically developed biotech rice and phytase corn (used for animal feed), although further approvals are required before the crops can be grown on a commercial scale (Batson and Areddy 2009).[21]

A science-based, efficient, and transparent regulatory system is essential for private and public sector firms seeking to introduce new biotech seed technologies on the market, as well as for farmers and the consuming public. In both China and India, however, regulatory systems reportedly have been used to block market access for global firms and to favor domestic ones. Regulatory review in India has been reported to take into account the way in which a product will be commercialized, including whether a global firm would have market exclusivity in the event of an approval and thus the ability to charge particularly high prices. Regulatory approval reportedly has been delayed or denied to avoid such a possibility. [22]

[21] China's actions may have been motivated in part by European Union reports that, as early as 2006, genetically modified rice had begun to show up in China's exports. China may have a significant interest in avoiding the perception that its regulatory system is not appropriately reviewing and controlling biotech crops. Industry representative, interview by Commission staff, Beijing, October 22, 2009.

[22] Industry representative, telephone interview by Commission staff, June 10, 2009.

TABLE 2 India: Biotech crops in field trials, 2006–2009

Crop	No. of Public/Private Organizations	Trait
Eggplant	Public (3) Private (3)	Insect resistance
Cabbage	Private (2)	Insect resistance
Castor	Public (1)	Insect resistance
Cauliflower	Private (2)	Insect resistance
Corn	Private (3)	Insect resistance, herbicide tolerance
Cotton	Public (1) Private (4)	Insect resistance, herbicide tolerance
Groundnut	Public (1)	Virus resistance Drought tolerance
Okra	Private (4)	Insect resistance
Potato	Public (2)	Disease resistance
Rice	Public (4) Private (3)	Insect resistance Disease resistance Virus resistance Drought tolerance Fortified food Hybrid improvement
Sorghum	Public (1)	Insect resistance
Tomato	Public (1) Private (2)	Virus resistance Insect resistance Drought resistance

Sources: Indian GMO Research Information System Web Site; James 2008.

The product that appears closest to regulatory approval in India is Bt eggplant, which uses technology similar to that in Bt cotton and is sponsored by Mahyco. Mahyco also has donated the Bt eggplant technology to public research institutions in India that are developing OPVs (rather than hybrids) that will be made available to poor farmers for saving and reuse. Mahyco started R&D work on Bt eggplant in 2000, and the product has moved slowly through the regulatory pipeline (Choudhary and Guar 2009, 43-45, 54). Although the Genetic Engineering Approval Committee (GEAC) approved the product October of 2009 after lengthy review, shortly thereafter India's environment minister put the approval on hold pending further consultations (GMO Safety 2009).

In China, the Ministry of Agriculture recently announced biosafety approvals for genetically modified phytase corn and rice. Phytase corn, developed by the Chinese Academy of Agricultural Science and sponsored by Origin Agritech, is intended for use in animal feed to limit the need for phosphate supplements, and thereby reduce feed costs and environmental impacts. Origin has noted in its corporate filings that the fact that foreign-funded companies are restricted to early-stage R&D activities has given it a substantial competitive advantage over global biotech companies (Origin Agritech 2008, 69). With regard to biotech rice, the Ministry of Agriculture noted that its recent approval: "is an important achievement in independent intellectual property from our country's research into genetic modification technology" (Batson and Areddy 2009). Both India and China thus have recently focused on moving domestically developed products forward in their regulatory pipelines.

Illegal Seeds in India and China

The spread of illegal seeds remains a substantial and ongoing problem in China and India. Some illegal seeds violate IP laws while others violate regulatory requirements that biotech products be reviewed and approved before commercial release. Examples of illegal seeds that violate IP laws are those mislabeled to confuse the consumer into believing that he is buying a legitimate product, as well as legitimate products that have been misappropriated, for example by theft from breeders' fields. A description of the market for illegal cotton seeds in India is provided below, box 1.

Illegal seeds are also a significant problem in China. With regard to biotech cotton, the problem may be even more prevalent than in India because the genetics were originally inserted into OPVs—which can be saved and reused in subsequent seasons—rather than hybrids. Based on a sample of farmers surveyed in five provinces in Northern China in 1999–2001, Hu and others (2009) measured the incidence of legitimate and illegitimate versions of domestic Bt cotton (the public sector variety developed by CAAS) and foreign Bt cotton (the Monsanto product marketed by Chinese joint ventures). Illegitimate seed was more prevalent than legitimate seed in Henan (83 percent of sampled households), Shandong (60 percent), and Jiangsu (56 percent) provinces, while legitimate seed dominated markets in Hebei and Anhui provinces (where Monsanto's joint ventures had a strong local presence).

BOX 1 Illegal and counterfeit cotton seeds in India

Illegal cotton seeds reportedly were grown in the Indian state of Gujarat beginning in 1999 and officially discovered in 2001, all while a legitimate Bt cotton product from Mahyco-Monsanto Biotech (MMB) was under regulatory review. The illegal seed was identified as NB 151, a variety registered as a conventional hybrid by NavBharat Seeds but containing the Bt genetics developed by MMB.

NavBharat Seeds was banned from the cotton seed business and prosecuted for violating biosafety laws, but the production, distribution, and widespread use of NB 151 reportedly continues. The seed is produced and distributed through a network of seed companies, producers, and agents, many of whom are former contract growers for NavBharat Seeds.

Illegal Bt cotton seed production and sales are thought to be concentrated in Gujarat and, to a lesser extent, in Punjab, Maharashtra, and Andhra Pradesh. According to surveys conducted by Lalitha, Pray, and Ramaswami (2008), the area covered by illegal Bt exceeded the legal Bt area from 2002/03 until 2005/06. The area planted in illegal seeds declined to 34 percent of the total area planted in Bt cotton in 2006/07, and was forecast to further decline to 27 percent in 2007/08. While illegal seeds are still prevalent, price restrictions appear to be having the positive effect of making the legal product more price competitive with illegal Bt cotton.

Counterfeit cotton seeds also are a substantial problem. Dealers label counterfeits with names similar to well-known Bt cotton sources—for example, “Mahaco” rather than “Mahyco.” The counterfeits do not carry the insect-resistant trait of legitimate products. “Brown bagging,” where farmers and others sell repackaged proprietary seed and seed of unknown origin in village markets, is also a common practice, with Bt and non-Bt cotton seeds mixed indiscriminately.

Sources: Lalitha, Pray, and Ramaswami (2008); and Herring (2009).

The prevalence of illegal seeds reduced benefits from the adoption of Bt cotton. Using regression analysis, Hu and others found that farmers who used legitimate seeds used fewer pesticides and obtained higher yields when compared to those who used illegitimate seeds. Moreover, farmers who obtained their seeds from commercial channels rather than from state actors or seed exchange obtained better yields, as did farmers who chose the Monsanto rather than the CAAS varieties (Hu et al. 2009, 801). These empirical results provide strong support for the conclusion that better IP enforcement and regulatory oversight to ensure that farmers are using legitimate and approved products, as well as reform of the seed industry to permit more foreign participation in China, could improve the production efficiency of cotton and other biotech crops.

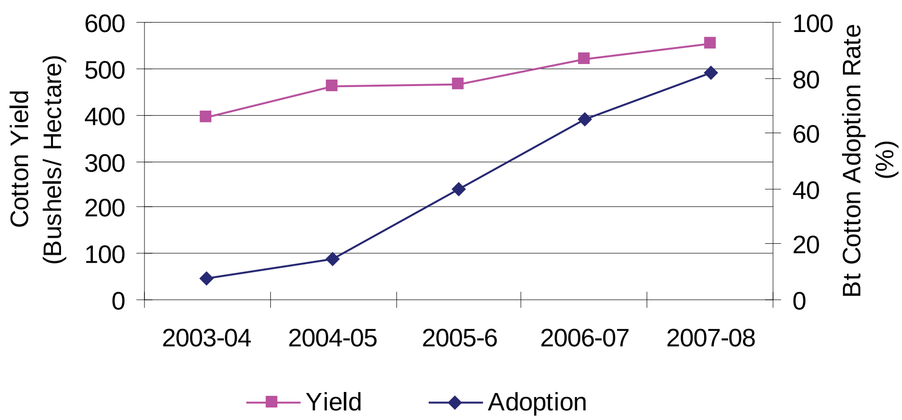
The Adoption of Bt Cotton in India and China: A Case Study

Bt cotton has been the first, and only, widely commercialized biotech crop planted in India and China. While the product has been developed and introduced differently in the two countries, one commonality is notable: the accrual of benefits to farmers in terms of increased profits and yields. We begin with a discussion of these benefits, and then turn to a description of the uptake of Bt cotton in both countries, with a focus on the factors identified as important—market access, IP protection, and regulatory review. The paper concludes with a general assessment of the ways the two countries' policy environments support (or fail to support) seed innovation.

Benefits from the Adoption of Bt Cotton in India and China

Bt cotton was approved for commercial release in India in 2002, and farmers grew about 50,000 hectares of it in the first year. Adoption increased rapidly over the next years. By 2008, 7.6 million acres were planted in Bt cotton, representing 82 percent of all cotton planted that year. Increases in yield went hand in hand with increased adoption. Prior to Bt cotton, India had one of the lowest cotton yields in the world—308 kg per hectare in 2001/02; yields are expected to reach 591 kg per hectare in 2008/09 (figure 5). India also moved from being an importer of cotton in 2002 to a substantial exporter by 2008 (James 2008, 52).

FIGURE 5 India Cotton Yield and Bt Cotton Adoption Rate, 2003–08

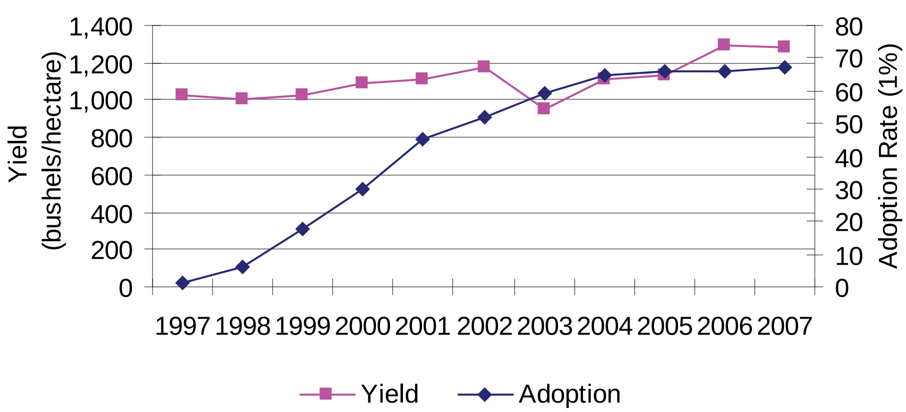


Source: Indiastat.com

The increased use of Bt cotton also has coincided with a significant decrease in pesticide use. Historically, cotton had consumed more insecticides than any other crop in India. The market for insecticides for bollworm (the pest to which Bt cotton is targeted) declined from $147 million in 1998 to $65 million in 2006, despite the fact that the total area planted in cotton increased. As a result of the increased yields and the decreased use of pesticides, cotton farmers made more money. The adoption of Bt cotton reportedly generated economic benefits of $3.2 billion from 2002 to 2007 (James 2008, 43, 51).

In China, Bt cotton was approved for use in 1996, making China one of the six "founder biotech crop countries" that approved biotech crops in the first year of their global commercialization (James 2008, 88). Cotton is primarily grown in the provinces of Hebei, Henan, Shandong, Anhui, Jiangsu, and Shanxi; Bt cotton adoption rates in these provinces are generally above 80 percent. Adoption rates are much lower (about 10–15 percent) in Xingjiang province, where the cotton bollworm is not considered to be a major problem (James 2008, 90). Overall, the adoption rate in China has held relatively steady in recent years at about 66 to 69 percent, figure 6.

FIGURE 6 China cotton yield and Bt cotton adoption rate, 1997–2007



Source: CEIC China Database.

China did not start from the same low levels of productivity in cotton as India and thus has not experienced such dramatic yield increases. Based on studies conducted by the Center for Chinese Agricultural Policy, Bt cotton has increased average yields by 9.6 percent, reduced insecticide use by 60 percent and, at the national level, increased income by approximately $800 million per year (James 2008, 97). The substantial benefits derived from Bt cotton underscore the importance in both countries of getting the policy environment right for innovation in biotech seeds.

The Impact of Government Policies on the Adoption of Bt Cotton

Domestic and foreign firms spearheaded the adoption of Bt cotton in India. The Indian public sector had little involvement in the product's R&D and commercialization; the Indian government's Department of Biotechnology (DBT) rejected an offer from Monsanto to collaborate on biotech crops (table 3). In 1995, Mahyco obtained permission to import Bt cotton technology from Monsanto. R&D began, and in 1998 Monsanto purchased a 26 percent share in Mahyco. The two companies then formed Mahyco-Monsanto Biotech (MMB), a 50:50 joint venture to commercialize biotech products in India (Scoones 2003, 7).

MMB obtained regulatory approval for Bt cotton in 2002, about six years after it began field testing of the product. Thereafter, MMB licensed the technology to other domestic and foreign firms for use in their own hybrids. Today, Bt cotton products have been commercialized in India by 30 companies in a total of 274 hybrids. Domestic firms also have obtained approval for two new Bt cotton "events,"[23] including one sourced from CAAS. In 2008, the Indian public sector obtained regulatory approval for its Bt cotton event, with genetics inserted into OPVs that farmers can save and reuse (James 2008, 56).

IP protections did not play a central role in the initial introduction of Bt cotton in India. The MMB Bt cotton events were inserted into hybrids, which have natural, built-in protection mechanisms against appropriation by farmers and competitors. Moreover, patent protections were not available for biotech products at the time Bt cotton was introduced, and the plant variety protection system was not put into place until 2007. [24]

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[23] Biotechnologists refer to the transfer of a particular genetic sequence into a plant as an "event."

[24] Patent protection was available for some biotechnology processes rather than products, and Monsanto and other firms obtained patents for processes. However, the infringement of process patents generally is more difficult to detect than that of product patents because it requires knowledge of a competitor's manufacturing methods rather than a comparison of the commercially available products.

TABLE 3 Bt Cotton in India: Chronology of Events

Date	Events
1990–1993	Monsanto approaches the Indian government's Department of Biotechnology (DBT) to collaborate on the development and commercialization of Bt technology. Indian government rejects offer.
1995	Mahyco granted permission to import Bt cotton genetics from Monsanto.
1996	Monsanto's Bt cotton approved for commercial release in the United States.
1996	Mahyco develops three backcrossed lines using Monsanto genetics and its own cotton hybrids and begins biosafety testing.
1998	Monsanto acquires a share of Mahyco and they form MMB to jointly develop and commercialize biotech products in India.
1996–2002	MMB carries out field and biosafety trials to support the regulatory approval of Bt cotton.
2002	GEAC approves commercial release of MMB's Bt cotton for a three-year trial period in six states.
2006	GEAC approves Bollgard II, the second generation Monsanto product, and genetic events from JK Agri-Genetics and Nath Seeds.
2006–2008	GEAC approves a total of 274 Bt cotton hybrids commercialized by 30 different companies.
2008	GEAC approves Bt cotton genetics developed by public sector and inserted into OPV that can be saved and reused by farmers.
2009	Monsanto obtains Indian patent for genetics underlying the second generation of its Bt cotton product, Bollgard I.I

Sources: Scoones 2003; James 2008.

The slow-moving regulatory system did give some first-mover advantages to the MMB product. Domestic firms with Bt cotton events did not obtain regulatory approval to commercialize their Bt cotton technologies until 2006, four years after the approval of MMB's first product, Bollgard I. However, delayed approval of the MMB product also fostered a market in illegal seeds to satisfy unmet demand for the technology. Today, Bollgard II is patented in India, but illegal seeds are an ongoing problem because of the inadequate enforcement of IP laws and regulatory requirements.

The public sector has played a much larger role in the development and adoption of Bt cotton in China; the role of foreign firms has been substantially circumscribed (table 4). As in India, Monsanto initially attempted to collaborate with the government on biotech cotton but was turned down (after the technology was shared and field tests conducted). Monsanto and Delta & Pineland (another U.S. firm) then formed a joint venture called Jidai with the Hebei Provincial Seed Company to develop and distribute biotech seeds. The U.S. partners initially held a 67 percent share in the venture. Jidai obtained approval to market the Monsanto variety in 1997. The adoption of the Monsanto varieties was rapid in Hebei and later in Anhui and Shandong provinces (Karpus and Deng 2008, 88–89). In 1997, the Chinese government reduced to 49 percent the stake that a foreign firm could hold in a Chinese seed company, based on concerns that the foreign firms had too much of an upper hand in the Bt cotton collaboration (Keeley 2003, 22).

TABLE 4 Bt Cotton in China: Chronology of Events

Date	Events
Early 1990s	Monsanto and the Chinese government's Cotton Research Institute begin a joint research program on biotech cotton. The joint program dissolves in 1995.
Mid-1990s	Monsanto and Delta & Pineland form a joint venture with the Hebei Provincial Seed Company and set up a new company, Jidai, to test, obtain regulatory approval, and commercialize Bt cotton varieties. CAAS begins field-testing and commercialization of its own BT cotton varieties.
1996	Two CAAS Bt cotton varieties are approved for commercialization in nine provinces.
1997	Jidai obtains approval to market Bt cotton in Hebei province only. Rapid adoption of Monsanto product.
1997	Government reduces to 49 percent the maximum foreign ownership in seed companies.
1997–99	Slow initial adoption of CAAS products by local seed companies. CAAS sets up Biocentury Transgene Corporation to manage seed sales and licensing.
2002	CAAS receives marketing approval for its varieties in the Yangtze River Region; Monsanto joint venture does not receive approval.
2002	Chinese government issues FDI guidelines prohibiting foreign firms from setting up new joint ventures to commercialize biotech seeds.
2004–09	Bt cotton-related patents issued in China to CAAS, Monsanto, and other public and private sector firms.

Sources: Karplus and Deng 2008; Keeley 2003.

CAAS had its own public sector Bt cotton varieties in development simultaneously with the Monsanto product. The CAAS varieties obtained regulatory approval first and over a wider geographic area. However, CAAS had difficulties with marketing its products. As a government research institute, it reportedly did not have the distribution networks or relationships needed to efficiently bring its varieties to market. CAAS addressed the problem by taking a major stake in Biocentury Transgene Corporation, a company formed to handle the sales of Bt cotton seeds (Karplus and Deng 2008, 88). Biocentury received substantial funding from the 863 program and other government funding programs. As a MOST official stated: “We gave them a title, they are a ‘National Development Base of the 863 programme,’ not an ordinary company, a national development base, that helps their business” (Keeley 2003, 19). Origin Agritech acquired a 34 percent stake in Biocentury in 2006, and now markets the CAAS Bt cotton varieties (Origin 2008, 45, 48).

The market position of the CAAS varieties has improved significantly in recent years. Today, domestic varieties of Bt cotton are estimated to hold 80 percent of the market, although official data are not available (Sanchez and Lei 2009, 5). Keeley attributes much of the CAAS success to strategic decisions by regulators to deny approval to the Monsanto product in a number of provinces, particularly in the Yangtze River cotton region. Although regulatory authorities justified the decisions on biosafety grounds, industry representatives were skeptical (Keeley 2003, 24). FDI guidelines issued in 2002 prohibiting foreign firms from commercializing biotech products further preserve the market dominance of Chinese firms.

IP protection did not play a central role in the initial introduction of Bt cotton into China. Plant variety protection has been in place since 1997; however, cotton was specifically excluded from coverage until 2005. Patent protection for biotech products was not available at the time of the initial release of the Monsanto and CAAS products. The fact that the Bt cotton events were in OPVs in China rather than hybrids as in India appears to have encouraged even more widespread use of illegitimate seeds in China.

Recently, Monsanto, CAAS, and others have obtained patents for their latest Bt cotton events. However, enforcement of IPR laws and regulatory requirements is an ongoing problem. While the initial regulatory approval of the Bt cotton technology occurred more quickly in China than in India, at the provincial level, the Monsanto product faced regulatory delays and denials that appear to have been unrelated to biosafety issues. These practices may undermine confidence in the regulatory system’s ability to regulate new biotech seeds in a fair and science-based manner.

Conclusions

This paper has compared and contrasted government policies in India and China to support innovation in the field of biotech seeds. Both countries have determined that biotech is an important tool for responding to substantial challenges in their agricultural sectors, and have put in place institutions and funding mechanisms to support R&D in agricultural biotechnology. India and China also have adopted policies in the areas of market access, IP protection, and regulatory review that have both fostered and discouraged innovation in biotech seeds.

China has established a central role for the public sector in controlling biotech seed innovation. Market access for foreign firms is severely limited. China's public sector takes a leading role in R&D and in the formation and support of firms charged with marketing biotech seeds. China's government research institutions and universities also are leading users of the patent and plant variety IP protection systems. China's apparent strategic use of regulatory review to deny market access to foreign firms has also buttressed the position of the public sector and its affiliated firms.

If judged by the strong market position of domestic varieties of Bt cotton, China's strategy of public sector dominance of biotech seeds has been successful. However, the fact that no other biotech products have been widely commercialized in the 13 years since the approval of Bt cotton suggests weaknesses in China's approach. China's recent decision to permit FDI in some biotech seed R&D projects is perhaps a recognition that closing the market to foreign participation also shuts off access to valuable technologies needed to address serious agricultural challenges. More cynically, it may represent an attempt to obtain access for domestic firms to the latest technologies. Improved enforcement of regulatory and IP laws is critical to ensure that only safe and legitimate products are permitted on the market.

By contrast, India has opened its seed sector to foreign participation on terms equal to those of domestic firms. However, strict price controls at the state level have undermined India's liberal investment environment and undermined the innovative efforts of both foreign and domestic firms. India's public sector has been much less active than China's in R&D and in obtaining IP protection for biotech innovations. The recent focus on the development and commercialization of genetic events for OPVs that will be made available to farmers at a reduced cost is an exception to otherwise lower levels of public sector participation. The enforcement of IP protections and regulatory requirements also remains a significant problem in India. Significant delays, and decisions that focus on factors other than biosafety, undermine confidence in India's regulatory system. Timely, science-based review of products that have languished in the regulatory pipeline for years would be an important improvement in India's innovation policy environment.

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