Innovation in Biotechnology Seeds: Public and Private Initiatives in India and China [1]

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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. The paper begins 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 and biotechnology to address these challenges. The paper next describes each country's approach to three supply-side factors identified by industry sources as important to innovation in biotech seeds: market access, intellectual property protection, and regulatory review processes. The paper concludes with a case study highlighting how these three factors impacted 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 supply-side factors identified by industry sources as important to innovation in biotech seeds: market access, intellectual property (IP) protection, and regulatory review processes. We conclude with a case study highlighting how these three factors impacted the introduction and adoption of the first widely commercialized biotech crop in China and India, Bt cotton.[1]

With regard to the three factors identified as important to biotech seed innovation, we find that 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, Indian state governments have implemented price restrictions that severely limit the ability of all firms to charge market prices for biotech seeds. We next find that both countries have patent and plant variety protection laws that provide some protection for new plant technologies. The public sector is an important user of IP protection systems, particularly in China. Foreign firms are active in seeking patent protections in both countries; by contrast, domestic firms are not active users of the patent system. With regard to regulatory review, both countries appear to be in a holding pattern; products sponsored by the public and private sectors are languishing in the review pipeline. Both countries consider factors unrelated to biosafety in determining whether to approve new biotech seeds, a practice that can cause unreasonable delays and undermine public confidence in the regulatory process. Both countries also have difficulties with the enforcement of IP and regulatory laws. Illegal seeds—those that violate IP laws and/or have not undergone regulatory review—are an ongoing and substantial problem in India and China.

Agricultural Challenges in China and India

India and China have achieved remarkable economic growth over the last decade; however, growth in the agricultural sector has lagged that in the general economy. 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 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

[1] Bt cotton is a genetically modified crop that includes a gene from the soil bacterium, *Bacillus thuringiensis*. The bacteria produce a protein that is toxic when ingested by certain Lepidopteran insect, particularly the bollworm. Cotton containing the Bt gene is able to produce the toxin thereby providing insect resistance to the plant (USDA, ERS 2009a).

2008). While in China, agricultural output has grown about 7 percent per year during the period 1997–2007 (USDA, ERS 2009b).

In both countries, the agricultural sector faces the tremendous challenge of producing more with fewer resources including diminishing per capita arable land and water. Climate change, plant diseases and pests, pollution, and depleted ecosystems resulting from the heavy application of fertilizers and pesticides present significant additional challenges (Tuli et al. 2009, 319). In an effort to overcome these obstacles, governments in both countries 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. Biotechnology enables the transfer of selected genes instead of transferring thousands of genes as occurs with traditional plant breeding methods. Moreover, by expanding the possible universe of transferable genes to include essentially any living organism, biotechnology enables the introduction of new beneficial traits that would be difficult or impossible to create through traditional breeding methods. First generation biotech crops include those that have been genetically engineered to improve resistance to insects and tolerance to herbicides, thus enabling farmers to use fewer pesticides and obtain higher yields. Genetic engineering to increase a plant's tolerance to drought and high salinity levels, as well as to improve the nutritional content of crops, are promising emerging areas of agricultural biotechnology (Giddings and Chassy 2009; CEI 2009).

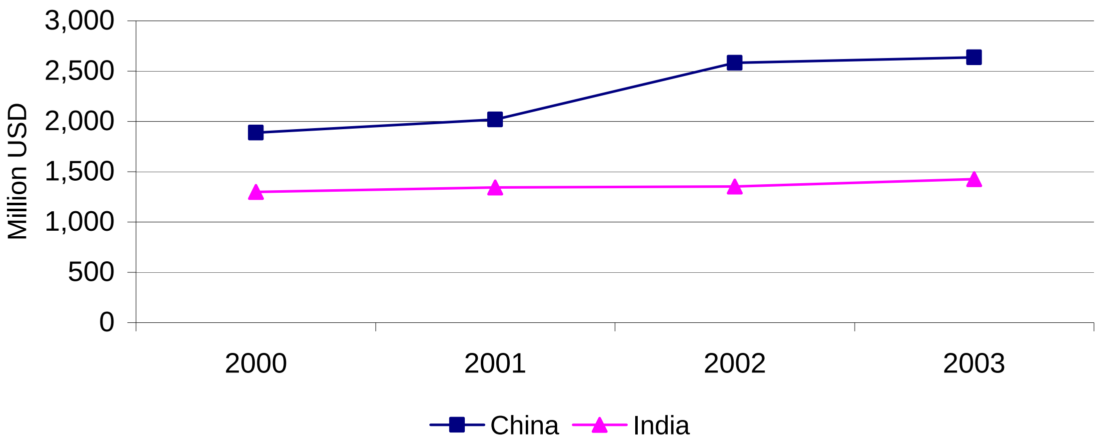
Government Investments in Agricultural Biotechnology

Increased agricultural productivity depends on R&D to support innovation. China and India have made significant investments in agricultural R&D. They are ranked 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).[2] Since 2000, agricultural R&D spending has grown much more rapidly in China, reaching $2.6 billion in 2003. By contrast, public sector R&D spending remained relatively unchanged in India during the period, figure 1.

Within the general field of agricultural R&D, China and India have identified biotechnology and genetic engineering as critical tools for overcoming the significant challenges to increasing productivity. According to a leading 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

[2] The authors' calculations are in international dollars, calculated by deflating expenditures in current local currency units using a local implicit GDP deflator for 2005 and then converting to international dollars using a 2005 purchasing power parity (PPP) index. PPP measures provide some advantages over market exchange rates: they are relatively stable over time and they take into account nontraded goods and services, which are often the largest components of a country's agricultural R&D expenditures (Beintema and Stads 2008, 4-5).

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



Source: ASTI database.

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). In addition to the DBT, 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).

There are few published estimates India's total R&D expenditures on agricultural biotechnology across the 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 5 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 the 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 and the Ministry of Agriculture. One of the most 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).

In recent years, China has elevated the status of agricultural biotechnology. 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" (James 2008, 93). Agricultural biotechnology is an important focus of China's Medium-and Long-term Science and Technology Development Plan (2006–20). In July of 2008, the Premier announced a budget increase for genetically modified crops of 4–5 billion RMB per year ($584-$730 million). One of the aims of this new initiative is 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 areas such as IP have a significant impact on innovation in agricultural biotechnology in China and India, as set forth below.

Government Policies Impacting 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.

Private Sector Access to Seed Markets in India and China

Seeds were predominantly a public sector business in India and China until recently; the situation has changed dramatically in India but not in China. Until the late 1980s, private firm participation in the seed industry in India was limited by economy-wide policies that restricted foreign investment and licensing and by 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 abolishment 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. They noted, however, that two factors were detracting from healthy competition: state level price caps placed on biotech cotton seeds and a substantial market in illegal seeds. Price caps were particularly problematic for new entrants to the biotech seed market, including JK Agri-Genetics and Nath Seeds, two domestic companies attempting to bring new biotech cotton seeds to market at the time that price caps were being implemented (Murugkar, Ramaswami, and Shelar 2007, 19–21).

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). 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 since spread to states throughout the country including Maharashtra, Gujarat, Tamil Nadu, Karnataka, Madhya Pradesh and West Bengal (Mishra 2006).

India's liberalized seed market (albeit with significant price controls) stands in stark contrast to that of China. Despite the enactment of a seed law in 2000 that creates a role for private firms, China continues to severely restrict FDI and the trading of certain types of seeds, substantially limiting the operations of global firms (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 in its geographic area. Although the 2000 seed law facilitated the marketing of seeds across geographic areas, according to field research conducted by Keeley (2003, 33–34) local markets remained difficult for non-local firms to access. 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 about the same time that Monsanto began to successfully market its biotech cotton product in China. In 1997, the year after the first approval of Monsanto's product, a new seed regulation required that any foreign company wishing to produce and sell cotton and other seeds 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). This new regulation required the reduction of Monsanto's 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 restrictions are repeated in the most recent FDI catalogue issued in 2007. With regard to conventional seed production, foreign firms are limited to minority shareholder status in joint ventures with Chinese partners (Petry 2007, 2).

The FDI restrictions reportedly arose out of Chinese government concerns about food security and the competitiveness of the 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 2009), for example, recently noted that seed is a strategic industry and that the opening up of the industry threatens the survival of domestic firms and the security of China's germplasm resources.

Notwithstanding the market access restrictions, foreign firms have been permitted to undertake several new biotech R&D projects in China. Reportedly, new investments are permitted if they are limited to research and experimentation, and do not extend to commercialization of new products.[3] 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 optimistic that the research they are permitted to do in China ultimately will lead to products they can commercialize there.[4]

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 is characterized by 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 of $5-10 million for the proof of concept phase, and $10-15 million for early product development (Monsanto India Ltd. 2009, 7). To obtain regulatory approval, Kalaitzandonakes, Alston, and Bradford (2007, 510) found that global seed firms incurred compliance costs ranging from $7–$15 million for herbicide-tolerant and insect-resistant corn submitted to regulators in ten countries. These large sunk R&D and regulatory compliance costs would be lost if competitors were permitted to free ride on the work of initial innovative firm.

An additional challenge arises from the "natural appropriation problem" of seeds (Maskus 2004, 722). OPVs can be reproduced simply by their cultivation and reuse and biotech seeds can be relatively easily copied by competitors through 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 the parental lines physically secure reduces the appropriation problem (World Bank 2006, 7–8). However, these built in protection mechanisms have their 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

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

[4] China does not have price controls regulating the cost of biotech cottonseed. However, government decisions at the local level about which seeds will be subsidized reportedly can be biased and based on connections rather than on product quality. Industry representative, telephone interview with Commission staff, July 24, 2009.

members 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). There is an exception to this general rule of patentability for plants and animals; however the exception is limited: patents must be provided for certain biotechnology processes for the production of plants and animals. Moreover, if a member country does not provide patents for plant varieties, it must provide an effective sui generis [or alternative] system (TRIPS, art. 27.3(b)). Some countries, including the United States, extend both patents and an alternative system to the protection of plants. Most developing countries, including India and China, provide only an alternative system, using the model supplied by the International Convention for the Protection of New Varieties of Plants (UPOV).

The TRIPS requirement that patent protection be provided for micro-organisms and non-biological and micro-biological processes for the production of plants should encompass many biotechnology products and processes. It is left to each WTO member, however, to determine if a particular product or process is novel, inventive, and has an industrial application, and to interpret essential terms such as micro-organisms, non-biological and micro-biological.

Patents in India and China

Both India and China exclude plants and seeds from patent protection but provide patents for micro-organisms, and non-biological and micro-biological processes that are inventive, novel, and have industrial application. However, global seed firms have expressed concern about the actual scope of coverage for biotechnology products and processes in both countries.[5]

In China, patentable genetic sequences must be “separate or extracted from nature for the first time, their sequences of base groups must not have been recorded in the literature, [and they] must be accurately characterized and have industrial value” (Zhan 2008, 35). Otherwise, a genetic substance will be considered a scientific discovery and not patentable. In India, a government-appointed expert group recently advised that strict guidelines should be followed in cases of micro-organisms and biotechnology processes to ensure “substantial human intervention and utility” (Technical Expert Group on Patent Law Issues March 2009, 15).

India and China’s cautious approaches have not prevented the granting of 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.[6] For example, it has obtained a patent for “Cotton Event Mon15985,” the genetics underlying the second generation of its biotech cotton product, as well as patents for biotechnology processes used in producing plants with herbicide tolerance, improved germination rates, and other valuable traits. Patents for other biotechnology methods for

[5] 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 too open-ended, ambiguous, and burdensome. Patent law provisions in both countries that permit compulsory licensing under a wide variety of circumstances also give rise to industry concerns. See BIO 2009, 2-3; industry representatives, e-mail message to Commission staff, June 19 and August 18, 2009; and industry representatives, telephone interviews by Commission staff, August 10, 2009.

[6] 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/patsea.htm (accessed July 12, 2009). Although date parameters for new records are not provided, they appear to comprise patents granted since 2007. Patents related to fertilizers, pesticides, and other agricultural chemicals are not included in the totals reported here.

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 patent applications pending for seed technologies.[7]

By contrast, most large domestic 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 pending applications for biotech seed technologies. Public sector research institutions, such as the Indian Council for Agricultural Research (ICAR) and the Council for Scientific and Industrial Research (CSIR) hold few patents or applications for biotech seed technologies at the Indian patent office.[8]

In China, there is substantial patenting of seed biotechnologies by foreign firms, figure 2.[9] Monsanto has the largest number of granted patents and pending applications. For example, it has obtained patents related to its insect resistant cottonseed 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 but have 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.

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, establishes that Chinese research institutes and universities are particularly active, figure 3. The research institutes of CAAS including the Biotechnology Research Institute (BRI), as well as Huazhong Agricultural University, and Central-China Agricultural University all hold multiple patents or applications for Bt-related technologies. The BRI reportedly generated about 15 percent of its income through patents in 2006 and expected to increase that share significantly in the near future (World Bank 2006, 38).[10] 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 the substantial patenting by Chinese research institutes and universities.

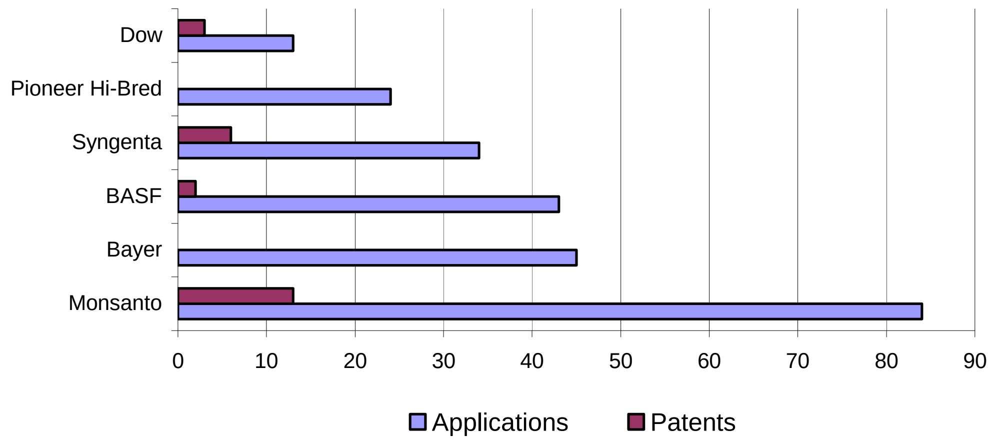
[7] India Big Patents Web site. http://india.bigpatents.org (accessed July 20, 2009).

[8] 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).

[9] Agricultural biotechnology patents were identified by review of 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 data base, http://search.cnpat.com.cn (accessed August 15, 2009).

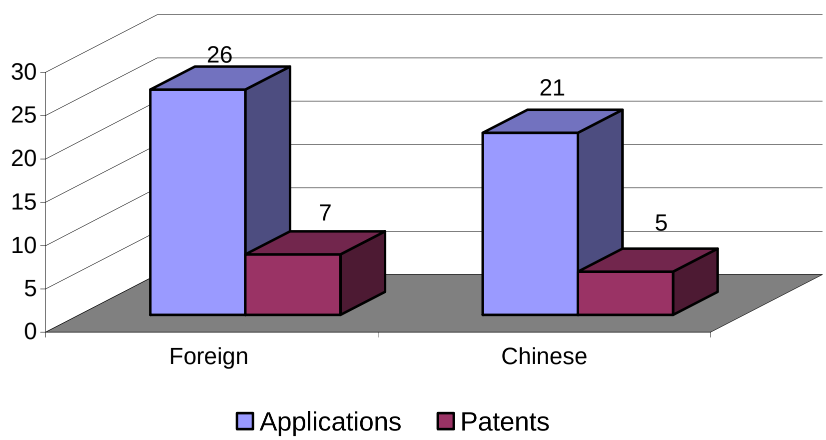
[10] As described in the case study, China's public sector actors have licensed the Bt technologies to firms that market and distribute the seeds.

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



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

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 laws as an alternative to the provision of patent protection for plant varieties. These laws provide marketing rights to developers of new plant varieties that are distinct, uniform, and stable.[11] However, the rights granted contain significant limitations and are generally considered weaker than patent rights, table 1.

China enacted its Plant Variety Protection Act (PVPA) in 1997 and began accepting applications to register new varieties in 1999.[12] India enacted legislation in 2001, the Protection of Plant Varieties and Farmers' Rights Act, 2001 (PPV&FR law), but did not begin accepting applications for the protection of plant varieties until May 2007.[13] Major differences between plant variety protection laws in India, China, and the United States are highlighted below (table 1).[14]

TABLE 1 Major differences in plant variety protection 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 eligible.	73 crops eligible.	No crops excluded.
Farmer seed saving and exchange	Seed saving, exchange, sale by farmers broadly permitted. Farmers only prohibited from selling "branded seed."	Farmer seed saving and exchange permitted, if non-commercial.	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.

[11] 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).

[12] 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).

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

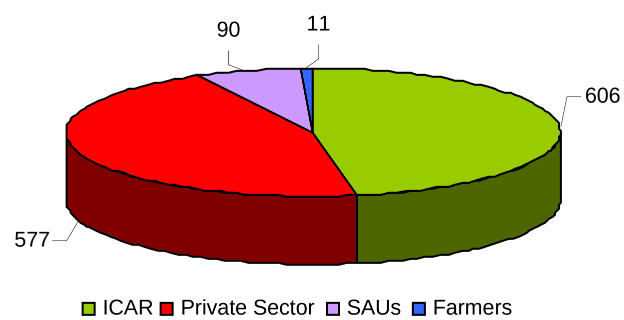
[14] The UPOV Convention, which has undergone several revisions since its enactment in 1961, serves as the model for plant variety protection in China, India, and the United States. The United States follow the latest revision, UPOV 1991, which is the most protective of the rights of plant breeders. China follows an earlier version, UPOV 1978, and India's PPV&FR law, while loosely based on UPOV 1978, contains broad exceptions intended to protect farmers. India's application to join UPOV has not been approved to date, apparently because of deviations from UPOV 1978. Government official, interview by Commission staff, Alexandria, VA, July 20, 2009.

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, 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) to enable the unrestricted spread of the first generation of biotech cotton technologies.

The most significant difference in PVP laws in the three countries is the breadth of farmers' privileges in India's law. Indian 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 farmer seed saving and informal exchange but prohibits commercial sales. U.S. law is significantly more restrictive; farmers can only save seed under specific conditions and new varieties cannot be "essentially derived" from protected varieties without a sharing of benefits. Global seed firms note that the broad farmers' privileges and breeders' exemptions render plant variety protection of limited commercial value in both India and China.[15]

Unlike in the United States, the dominant users of the plant variety protection systems in India and China are public research institutions and universities, seeking protection for conventional hybrids and OPVs rather than biotech plants. In India, most applications have been filed by the Indian Council of Agricultural Research (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.

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



Source: Indian PPV&FR Authority.

[15] 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.

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 from 1999–2004. This figure actually understates public sector involvement as approximately one 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 PVP 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 PVP 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 the private sector accounts 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 operate not only to stimulate private sector R&D but, even more importantly based on user statistics, to stimulate public sector involvement in the development of new plants.

Regulatory Review

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

India and China (and the United States) 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 multiple 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 in a particular state or province. In China, these procedures can add another 2-3 years to the time to market (Petry and Bugang 2008, 8).[16]

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

[16] By contrast, regulatory compliance procedures appear to take much less time in the United States. Jaffe (2006, 748) calculated the period of time from the official submission of a regulatory package for a biotech crop to the final agency decision allowing the product to be commercialized. The 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 from 1994–2005. However, the trend is for review time to increase; the time it took the agency to reach a regulatory decision more than doubled in 2001–2005, when compared to the previous five year period (Jaffe 2006, 748).

India in 2003 after approximately nine years of review and testing and millions of dollars in costs. Bayer reported that the continued costs, uncertainty about whether the product would ever be approved, and the potentially small market size all contributed to 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.

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. In China, Bt cotton, approved in 1996, is the only widely planted biotech crop. Table 2 identifies crops undergoing field trials in India. Most of the new biotech crops in the pipeline (24 of the 38 identified products) are from the private sector. China does not regularly publish lists of crops undergoing testing (Petry and Bugang 2008, 4); according to reports, however, stress and herbicide-tolerant rice, disease resistant cotton, insect resistant corn, quality improved corn, herbicide tolerant soybeans, virus resistant wheat, quality improved potato, insect resistant poplar trees and many other crops have entered or even completed trials (Karplus and Deng 2008, 104).

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

Crop	No. of Public/Private Organizations	Trait
Brinjal	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; James 2008.

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, 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 manner 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.[17] In China, insect and virus resistant rice has been in development and field trials since the 1990s. Several varieties completed pre-production trials in the early 2000s and have been awaiting approval for commercial release since then, with no articulated biosafety reason for the delay (Karplus and Deng 2008, 102–03).

The products that appear closest to regulatory approval, Bt brinjal in India and phytase maize in China, are those sponsored by domestic firms. Bt brinjal uses technology similar to that in Bt cotton, and was first developed and submitted for approval by Mahyco. Mahyco also has donated its 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 brinjal in 2000 and the product has moved slowly through the regulatory pipeline (Choudhary and Guar 2009, 43-45, 54). Although it was expected to be approved for commercial release in 2009, the Genetic Engineering Approval Committee (GEAC) recently announced the need for a new study of the socioeconomic impact of the product (notwithstanding the free transfer of technology to the public sector), postponing approval for the near future (Indian Express Finance 2009). In China, Origin Agritech has stated that its biotech phytase maize is in the final stage of regulatory approval for use as animal feed. Origin expects to commercialize the product by the end of 2009. According to Origin, the fact that foreign funded companies are restricted to early stage R&D activities provides it with a substantial competitive advantage over global biotech companies (Origin Agritech 2008, 69).

Illegal Seeds in India and China

The spread of illegal seeds is a substantial and ongoing problem in China and India. Illegal seeds include those that violate IP laws and those that 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. The market for illegal cottonseeds in India is described below, box 1.

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

BOX 1 Illegal and counterfeit cottonseeds in India

Illegal cottonseeds reportedly were grown in the Indian state of Gujarat beginning in 1999 and officially discovered in 2001, all while Mahyco-Monsanto Biotech's (MMB) legitimate Bt cotton product 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 cottonseed 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 cottonseed 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 cottonseeds 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 cottonseeds mixed indiscriminately.

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

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 collected 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).

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 seed 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 saving and 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 significantly improve the production efficiency of cotton and other biotech crops.

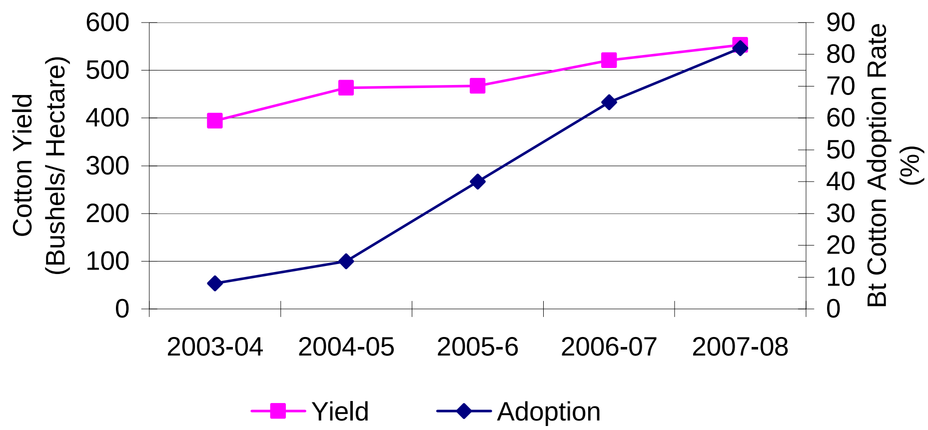
The Adoption of Bt Cotton in India and China: A Comparative Case Study

Bt cotton has been the first, and only, widely commercialized biotech crop 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 two countries' policy environments in place 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; it is expected to reach 591 kg per hectare in 2008-09, figure 5. India also moved from 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

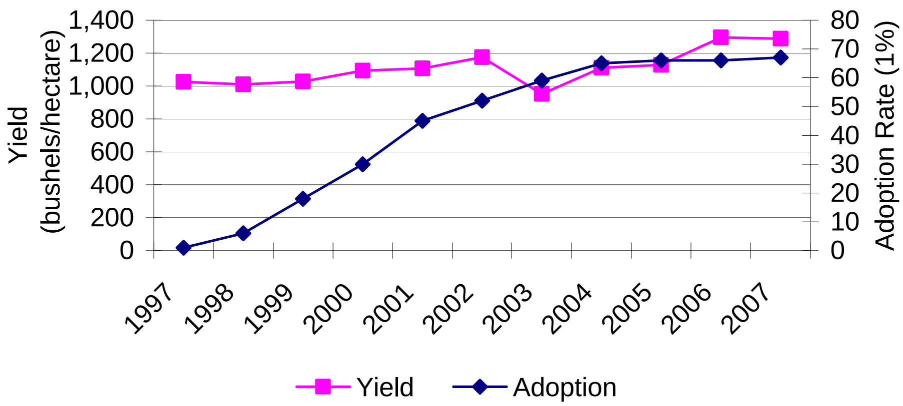


Source: Indiastat.com.

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) has 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 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 generally are above 80 percent. Adoption rates are much lower in Xingjiang province (about 10–15 percent), 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 the same 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. In 1995, after the Indian government's Department of Biotechnology (DBT) rejected an offer from Monsanto to collaborate on biotech crops, Mahyco obtained permission to import Bt cotton technology from Monsanto, table 3. 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 approval for Bt cotton in 2002, about 6 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,"[18] including one sourced from the Chinese Agricultural Academy of Science (CAAS). In 2008, the Indian public sector obtained regulatory approval for its Bt cotton event, with genetics inserted into OPVs that can be made available to farmers for them to save and reuse (James 2008, 56).

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	Mayhco granted permission to import Bt cotton genetics from Monsanto
1996	Monsanto's Bt cotton approved for commercial release in the United States.
1996	Mayhco develops 3 backcrossed lines using Monsanto genetics and its own cotton hybrids and begins biosafety testing
1998	Monsanto acquires a share of Maycho 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 3-year trial period in 6 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 II.

Sources: Scoones 2003; James 2008.

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.[19]

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, 4 years after 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.

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

[19] 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 the methods by which a competitor is manufacturing rather than a comparison of the commercially available products.

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
Mid-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 BT cotton varieties.
1996	Two CAAS Bt cotton varieties approved for commercialization in 9 provinces.
1997	JiDai obtains approval to market Bt cotton in Hebei province only. Rapid adoption of Monsanto product. Government reduces to 49 percent the maximum foreign ownership in seed companies.
1997–1999	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 turned down.
2002	FDI guidelines issued to prohibit foreign firms 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 simultaneous with the Monsanto product. The CAAS varieties obtained regulatory approval first and over a wider geographic area. However, CAAS had difficulties with marketing of its products. As a government research institute, it reportedly did not have the distribution networks or relationships needed to quickly 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 as well (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 is 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 inserted into OPVs in China rather than hybrids as in India appears to have encouraged even more widespread appropriation of the technologies. Recently, Monsanto, CAAS, and others have obtained patents for their latest Bt cotton technologies. 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 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 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 substantial 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. Improved enforcement of regulatory and IP laws also is critical to ensure that only safe and legitimate products are 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 negatively impacted 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. Delays and decisions that focus on factors other than biosafety undermine regulatory confidence. 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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