

**China's Regulation of Biotechnology – Does it Conform to the WTO?**

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### **Abstract:**

The People's Republic of China has been working for over two decades to develop a domestic biotechnology industry. Even though China is a developing country, it is set to become a significant international player in the field of biotechnology. China's accession to the World Trade Organization in December of 2001 means that China's trade and regulatory regime should now reflect its WTO commitments. This paper outlines the development of the Chinese biotechnology industry and how it may evolve in the future. It assesses China's current approach to trade and regulation of biotechnology in relation to GATT rules on trade in goods and the TRIPS commitments pertaining to the protection of intellectual property. The conclusion is that China's trade and intellectual property regimes currently deviate considerably from WTO norms and number of trade disputes are likely to arise in the near future.

Keywords: biotechnology, China, intellectual property, WTO

## **China's Regulation of Biotechnology – Does it Conform to the WTO?**

### **Introduction**

The People's Republic of China represents an important and growing market for the use and import of biotechnology products. Further, considerable investment has been made to develop an indigenous biotechnology industry. China, however, has not been immune to the general international debates surrounding trade in the products of biotechnology (Gaisford et al., 2001). In addition, China has only recently joined the World Trade Organization (WTO) and is currently attempting to manage the extensive trade liberalization that was a pre-condition for its accession. According to China's trading partners, progress in conforming to WTO norms has been slow and a number of impediments remain before China can be considered fully integrated into the international trade regime. Both China and its trading partners stand to reap large economic benefits if foreign biotechnology industries are allowed access to the Chinese market. To fully reap the benefits associated with the Chinese market, a liberal trade regime and strong protection for foreign intellectual property are required. As a result, the regulatory framework that is evolving in China and, particularly, the enforcement of its rules, will require considerable additional effort if international norms are to be achieved (USTR, 2003a).

In addition to the extensive changes involved in moving China's economic system from central planning and command to *market socialism*, its international trading and domestic regulatory regimes have had to undergo fundamental changes in recent years as a result of its WTO accession commitments. Not only did China have to reduce or eliminate a wide range of trade barriers and open its domestic industries to increased

competition, it also had to modify and add to domestic legislation in order to be in compliance with WTO protocols, including those pertaining to the protection of intellectual property (USTR, 2003a). China's central government has also committed to additional reforms to reduce the state's role in the economy to satisfy both domestic and international calls for a more market-based system. These changes will include further separating government from business, privatizing additional state enterprises, fostering a more independent central banking system and reducing corruption (The Economist, 2001a).

To fully understand the potential obstacles to the development of trade in the products of biotechnology with China, its trade history, trade policies and practices, market significance, biotechnology industry and domestic regulation as well as issues surrounding government and private sector compliance with international obligations and domestic law must be considered. The international obligations that will have the most profound effect on trade in the products of biotechnology will be China's WTO accession agreement, general WTO norms regarding market access, the WTO's agreement on Sanitary and Phytosanitary measures (SPS) and the Agreement on Trade Related Aspects of Intellectual Property (TRIPS). The latter plays a very important role in the trade of knowledge goods such as biotechnology. Examining past conflicts surrounding China's trade with countries with advanced technologies helps shed light on where problems may arise again and how best to deal with them.

### **The Chinese Economy**

Within the next 20 years, China has the potential to become the second-largest economy of the world, second only to the U.S. (The Economist 2001a). If China fulfils its

WTO commitments and continues moves toward embracing a market based economy, its economy is expected to grow at 9 percent per year during 2006-2015, before slowing down a bit for 2015-2020. If so, by 2020 China's GDP would have grown to US\$10 trillion (The Economist, 2001a).

The Chinese economy has shown consistent growth since the government began dismantling its command economy in favour of markets and opening its markets to foreign goods and investment. Since 1990, the percentage increase in GDP on the year earlier has never been below 4 percent. In 1992, the growth rate peaked at 14 percent (The Economist, 2000). Between 1997 and 2000, the economy grew by 24.7 percent. The growth rate for each year between 1999 and 2002 was over 7 percent. These rates are far higher than most countries, including developed nations. In 2001, China was the world's fastest growing large economy (The Economist, 2002). Given China's large population and rapidly rising incomes, it is not surprising that firms in modern market economies, including biotechnology companies, are interested in being able to take advantage of opportunities that they perceive are available in the Chinese market..

### **The Chinese Biotechnology Industry**

Although almost one quarter of the world's total population lives in China, they live on only 7 percent of the world's arable land (Canadian Trade Commissioner Service, 2002). In addition, there has been a steady loss of arable land in China due to erosion, salinisation, desertification and urbanization. This loss has been at an alarming rate, estimated at 300,000 hectares per year (Kowalski, 2003). This creates the potential for serious social problems such as localized famines and food shortages, pollution and land degradation. The Chinese government views agricultural biotechnology as a tool to:

help improve the nation's food source, raise agricultural productivity, increase farmer's incomes, foster sustainable development, and improve its competitive position in international markets (Huang et al., 2001 p.1).

Advanced agricultural technology, such as biotechnology, will become critical for China's food security (Kowalski, 2003). In response, the government has made considerable resources available to the sector and actively promoted its development since the mid 1980s (Huang et al., 2001).

The biotechnology sector in China has enjoyed considerable scientific success and has grown to a considerable size but remains funded almost entirely by the government. Success has led to a rapid increase in support in recent years. In the second half of the 1990s, biotechnology spending more than doubled from the equivalent of US \$40 million to US \$112 million per year. The Chinese government has also promised to increase research budgets by 400 percent over the five-year period between 2002 and 2007. Even though China is a developing country, its total expenditures on agricultural research and development comprises an estimated 10 percent of global public expenditure (Gale et al, 2002). There are currently nearly 400 major biotechnology laboratories aided by the government and more than 20,000 research and technical personnel working in the industry (Wang, 2002). This research effort has yielded a wide array of genetically modified (GM) varieties that have gone through field trials, been cleared for environmental release and have been put into commercial production. Genetic modification has had a number of objectives (or combinations of objectives): insect resistance, bacterial-fungus resistance, virus resistance, salt tolerance, drought resistance, nutrition enrichment, quality improvement or yield increase (Chen and Qu, 2002). China has the fourth highest commercial acreage of transgenic crops, behind the U.S., Canada

and Argentina. China was the first country to grow a transgenic crop commercially – tobacco. After having 1.6 million hectares planted with GM tobacco in 1996, China discontinued growing the GM tobacco due to concerns that tobacco processors, mostly from the U.S., would ban Chinese imports of tobacco because it was genetically modified (Pray, 1999).

Six crops have been issued licences that permit commercial production. Two licences were granted for different varieties of insect resistant cotton. In 2000, GM cotton was planted on 700,000 hectares in China (Huang et al., 2001). Two licences were also granted to tomato varieties, one that is modified to delay ripening and one that is virus resistant. Colour-altered petunias and virus resistant sweet peppers have also been licensed. Monsanto, which is based in the US, holds the only license that has been issued to a foreign company for their variety of GM cotton (Chen and Qu, 2002).

There are still a large number of modified plants that have not yet been commercialized but are in field trials or have been cleared for environmental release. As of 1999, these included: two new varieties of insect resistant cotton; three varieties of disease resistant cotton; insect, disease and herbicide resistant rice; salt tolerant rice; improved quality and virus resistant wheat; improved quality and insect resistant maize; herbicide resistant soybeans; disease resistant potatoes; disease resistant rapeseed; virus resistant tobacco; virus resistant peanuts; virus resistant cabbage; cold tolerant and multi-virus resistant tomatoes; virus resistant melons; virus resistant papayas; insect resistant poplar trees; and bacterial resistant pogostemun<sup>1</sup> (Huang et al., 2001).

Non-agricultural uses of biotechnology represents a much smaller proportion of the industry than agricultural biotechnology but it is an important part of the government's

plan to alleviate some of China's most serious problems. In total, 18 bio-pharmaceuticals have been commercialized and 30 more are in clinical trials. Progress has also been made in development of bio-pesticides (Ju, 2001). A transgenic carp (China's most abundant aquaculture species) that will grow 42 percent faster than non-transgenic carp has also been developed (CAS, 1999).

Trade in the products of biotechnology is also increasing in importance. From January to April of 2003, biological technology imports equalled US \$36 million. During that same period, there were US \$60 million of biological technology exports. In April of 2003, biological technology imports decreased by 43 percent, partially due to seasonal factors but also due to changes in regulations and the uncertainty that these changes have caused. However, during the four month period beginning in January of 2003 and ending in April of 2003, there was a 6.9 percent increase in imports over the previous four month period. Exports showed much stronger growth. In April, there was a 23 percent increase from the previous month and January to April showed a 28 percent increase over the previous four months (Ministry of Commerce of the People's Republic of China, 2003). Soybean imports from the US alone, 70 percent of which are genetically modified, are over US \$1 billion per year. This is the single largest market for US soybean exports (Ohio Integrated Pest Management, 2002). China's most important GM export is cotton – 51 percent is genetically modified (Kyne, 2002).

#### *China's Biotechnology Policy*

The Chinese government's biotechnology policy will be an important factor in encouraging both private domestic production and international investment but, as yet, it is full of contradictions, ambiguities and lacks transparency, particularly for international

firms. Professor H.G. Wang (2002) of the China National Center for Biotechnology Development claims that:

[the] basic policy is to strongly support the Research and Development; prudently promote the application of biotechnology; ensure the bio-safety and promote sustainability of the bioindustry (p.2).

While the government of China provides considerable financial support for the biotechnology industry and makes extensive claims about the benefits biotechnology will bring to their society, when it comes to regulations, the commitment is less firm and increasingly opaque. The President of Monsanto in China, the firm that holds the only foreign GM licence, John L. Killmer states that, “[China has] one foot on the accelerator, which is funding biotech research and development, and they have one foot on the regulatory brake” (as cited in Dosh, 2003, p. 2). The lack of clear and consistent direction from the government creates an extremely risky business environment for those wishing to export GM products to China or to invest in biotechnology related activities, including research.

In January 2002, China published import regulations that required labelling and safety certification for all GM animals and plants entering China for sale, production, processing or research. Obtaining a certificate to import GM products is an complex process that may take up to 270 days and whose requirements can act as a significant trade barrier (Gale et al., 2002). Trade issues are dealt with at greater length later in this paper.

While imports have received the most scrutiny, domestic producers are not immune to regulatory hurdles. On May 23, 2001, the Chinese State Council promulgated the

“Regulations on the Safety of Agricultural Genetically Modified Organisms”. These regulations provided for:

largely similar, though somewhat less densely regulated, mechanisms and principle as the Swiss Ordinance on Releasing Organisms in the Environment or the European Union’s Council Directive on the deliberate release into the environment of genetically modified organisms (Kaiser and Thaler, 2001 p.1).

The general principles underlying these new regulations include that the biosafety of GM crops and other organisms, as well as the risks associated with them, should be assessed on a case-by-case, variety-by-variety, line-by-line basis and in a stepwise manner. Decision making should be based on demonstrated risks, biosafety reviews should focus on the scientific questions and data, an expert panel should play an important role in the decision-making process and regulatory requirements should be consistent, dynamic and transparent. When assessing the safety of a GM crop, regulators now base their decisions on several key parameters such as the characteristics of the organism, introduced trait and intended use, the interaction the organism will have with other environmental factors and the combination of all these factors (Cheng and Peng, 2002). Once these GM crops are approved and enter the Chinese market, they may also be subject to strict labelling requirements. State authorities are still working to establish and clarify the requirements that will apply to different classes of products (Kaiser and Thaler, 2001). The Chinese government hopes that these regulations will ensure the biotechnology products grown in China for both domestic consumption and for international trade will not pose risks to human health or the environment. These regulations have already been responsible for delaying several attempts to commercialize new varieties of crops such as rice and corn (Cheng and Peng, 2002).

In general, it appears that China is beginning to put in place increasingly stringent regulations on GM foods in particular. While widespread support and favourable policies have been granted for non-food GM products (such as cotton), both domestic and international food safety concerns have begun to influence the government's regulations and policies regarding GM foods (Gale et al., 2002). Some Chinese scientists argue that this more cautious approach is justified given that the next generation of GM crops includes staple foods such as rice which could be consumed by billions of people around the world and whose safety now rests in China's hands (The Economist, 2002).

#### *Consumer Acceptance of Biotechnology in China*

Acceptance of biotechnology by Chinese consumers carries with it enormous potential benefit to firms wishing to market biotechnology products. Consumer attitudes are heavily influenced by the government due to its control over the news media. A 1999 Environics International survey of consumers in 10 countries found that China had the highest consumer acceptance of biotechnology products of all the countries surveyed including the US., Canada, Japan, Russia, India, and four European countries (Gale et al., 2002). In a survey of 600 Asian consumers, including 200 Chinese citizens, 66 percent believed they would personally benefit from food biotechnology during the next five years, 55 percent believed they had eaten biotechnology foods recently and of those that had, 96 percent were satisfied with biotechnology products being available in their market and took no action to avoid them. When asked to spontaneously list advantages and disadvantages of biotechnology, five times more advantages were given than disadvantages. This survey also found that only 23 percent of respondents would prefer more information being included on food labels but when asked what information they

would like to see, not one respondent mentioned genetically modified ingredients. In general, concerns over possible negative side effects were expressed in a desire for more information and demonstrated a balanced and open-minded approach (Asian Food Information Centre, 2003). Of course, these are very small samples of the Chinese population and caution must be exercised in generalising the results.

Some exceptions to this positive view of biotechnology, however, appear to be emerging. Discussion of GM crops is increasing in the media. In January of 2000 the China Consumer Association issued a statement calling for labelling of genetically modified food products. The government has also begun to regulate the market. While the effects of this new legislation is not yet clear, it is apparent that China is stepping back somewhat from its unfaltering support for biotechnology (Canadian Trade Commissioner Service 2002). Due to the state control of the media, if the government position on biotechnology changes, consumer attitudes will almost surely change as well, producing a far less predictable commercial environment for biotechnology products (Gale et al., 2002).

#### *Looming Problems for China's Biotechnology Industry*

While the domestic industry, through generous support from the Chinese government, is becoming one of the major international biotechnology players, they face significant challenges and have some fundamental problems that must be remedied if it is to be successful in the long run. As mentioned above, almost all of the biotechnology programs have been fostered by the Chinese government. Subsidies, however, do not come without strings, particularly in a society where command from the centre has been the norm. As a result, there are many conditions attached to receiving subsidies and, in

particular, deciding which crops and traits research will focus upon<sup>2</sup>. While most biotechnology entrepreneurs would rather have private funds, private sector investors are reluctant to commit their resources until they know that the regulatory regime will give them a reasonable chance to be able to recoup their investment (The Economist, 2002).

Another significant challenge is managing the large and extremely complex agricultural biotechnology effort in China. Lack of coordination between the numerous divisions administering the program and between individual researchers has contributed to unnecessary and inefficient duplication of efforts, particularly at the local level. This results fewer, more expensive technology advances (Huang et al., 2001).

The Chinese government's failure to provide clarity regarding the future direction of regulatory policy has made foreign governments, particularly those in the European Union, extremely nervous that insufficient care will be taken in the design and enforcement of regulations to assure the food safety and environmental concerns of consumers and others in the European Union. As a result, they have been pressuring the Chinese government for stricter safety protocols. The government has not yet been able to find a good balance between ensuring their products are safe, satisfying international concerns and encouraging the industry to grow. If the balance cannot be found, not only will the public firms suffer considerably, meaning ongoing subsidies, the lack of certainty will discourage private domestic and foreign investment (Gale et al., 2002).

While the apparent acceptance of biotechnology products in China is a significant advantage at present, there is uncertainty over its long-term continuance. Although the limited information available suggests that Chinese consumers have a high level of awareness, they also have little accurate knowledge of GM foods. As Chinese consumers

have not been exposed to the debates regarding the safety of biotechnology, their views could easily be shifted if there were to be negative media coverage in the future (Gale et al., 2002).

The Chinese government has put regulations in place that restrict foreign investment in an attempt to ensure that what they perceive as a vital future industry remains under domestic control. The cost may be loss of opportunity for technology transfers (Kerr et al., 1997). On April 1, 2002, China enacted the “Catalogue for the Guidance of Industries for Foreign Investment”. This new regulatory regime prohibits foreign investment in the “production and development of trans-gene plants seeds” (Xiamen Foreign Investment Bureau, 2003a p.1). These regulations are the most restrictive regulations on the production, research and importation of genetically modified organisms (GMOs) in the world. While this will provide a short run benefit for the Chinese biotechnology industry because it will face no foreign competition in the lucrative seed-development business, they risk going it alone and failing. If China lags behind foreign seed providers, farmers may turn to illegally imported seed (Dow Jones Newswire, 2002).

Intellectual Property Rights (IPRs) will play an important role in the survival of the biotechnology industry and in ensuring that new innovations are made. In order to protect this knowledge-based industry, China must deal with serious deficiencies in domestic IPR laws. The question of IPRs is dealt with in greater detail later in the paper.

#### *Future Prospects for the Chinese Biotechnology Industry*

Despite the fact that the Chinese biotechnology industry is facing some significant challenges, it appears that its intermediate term prospects are relatively good. China is

still going through a period where deep and widespread changes in the way that its markets and international trade regimes operate, particularly regarding how the government can intervene in the economy (Kerr and MacKay, 1997). While in the long run, this change will almost certainly prove to be beneficial for both China and its trading partners, in the short run, the degree of uncertainty will limit enthusiasm for the Chinese market. One of the most critical factors for the biotechnology industry's long term success will be that motivation for success must come not only from the existence of profitable opportunities, as is the case in most developed nations, but also the realization that biotechnology could help solve some of China's most pressing social problems. As the Chinese population continues to grow and tax available food and land resources, even more attention will be placed upon finding alternative means to deal with these problems. Faced with these pressures, China is likely to give more weight to the extensive potential benefits of biotechnology (Gaisford et al., 2001) than developed countries while at the same time giving less weight to the risks.

As the government liberalises the economy, China seems ripe for increased private investment. The changes required to meet WTO obligations and Chinese firms having an increased ability to form joint ventures with other international firms will be the main inducements for foreign investors (Pray, 1999). The Law of the People Republic of China on Chinese-Foreign Contractual Joint Ventures, adopted on October 21, 2000 was designed to reduce the risk associated with forming joint ventures including protecting the lawful rights and interests of the international partner. There remains however, certain industries in which foreign investment is severely restricted or even prohibited, such as the production and development of trans-gene plants seeds (Xiamen Foreign

Investment Bureau, 2003b). The Chinese government must carefully consider policies that restrict foreign investment in the industry as it will: (a) irritate other governments, possibly to the point of filing an official complaint with the WTO and; (b) segregate their industry from advances made in other (most likely developed) nations that could cause the Chinese industry to fall behind its competitors (Dow Jones Newswire, 2002). In relation to the direction safety regulations will take, some optimism exists that the government will want to ensure that its enormous investment in biotechnology will pay off and will realize the danger they are putting their biotechnology industry in by instituting extremely restrictive policies and move to alter their regulations accordingly (The Economist, 2002).

### **Trade Issues Surrounding Biotechnology**

China has had to dramatically alter its trading practices, regulations, tariff system, non-tariff trade barriers, market structure and domestic legislation in order to be in compliance with their WTO accession agreement. While China has made considerable progress in moving toward compliance with the WTO's trade regime, the process has been difficult and may result in a considerable number of trade disputes. The Chinese government still frequently changes major policies affecting trade with little to no notice given to other members of the WTO. Even after these policies are made public, they are often vague and full of ambiguities. Rapid and unilateral shifts in trade policy and domestic policies that affect international commerce runs contrary to the WTO and will lead to complaints from China's trading partners.

Many of the most restrictive policies faced by firms wishing to export to China are a direct result of the pressure the government faces to provide strong domestic protection

(Canadian Trade Commissioner Service, 2002). While Chinese economic reforms have reduced the role of government, there is still a widespread expectation that the government should intervene when firms face financial difficulties. When China joined the WTO, they had to agree to reduce or eliminate a wide range of trade barriers. This has led many analysts to believe that the motivation for some of these new and confusing regulations is a way to circumvent China's WTO commitments and provide protection for their local industries. These technical and "scientific" barriers to trade have already been used to deny exporters of biotechnology access to the European Union market and many believe it is reasonable to assume that China sees it as a way to skirt around their obligations to open their markets to foreign competition (*Inside US Trade*, February 7, 2003). China has also been accused of making less stringent trade regulations for domestically manufactured products than regulations for their foreign counterparts, a particularly contentious issue in biotechnology trade (Canadian Trade Commissioner Service, 2002) and which runs counter to China's "National Treatment" commitments under the WTO.

### *China's Approach to International Trade*

The Chinese government's philosophy on international trade has been continuously evolving over the last two decades, ever since Deng Xiaoping's "opening to the world" in late 1978. A regime of tight government control in a closed economy has developed into a regime that is allowing more and more price setting through markets and an economy that welcomes foreigners, but only within closely prescribed limits. This change has not been brought about by a change in political ideals, but rather, because politicians' realization that their citizens demanded significant economic growth that

would only be possible through increased international integration. The Chinese government, however, does not perceive trade as serving the same role as (most) governments of modern market economies. While a liberal trade regime is accepted in developed economies because it means lower prices and more choice for consumers, China see trade as a means to achieve its economic development aspirations. China enters into trade to acquire the technology it needs to develop (Kerr and Hobbs, 2001). It does not want the foreign exchange acquired through the exports frittered away on the importation of consumer goods. Instead, foreign exchange should be used to acquire technology. This difference in philosophy leads China to be more interventionist in their trade regime than those of developed market economies. It also leads to potential disputes at the WTO. Further, China's experience with trade regimes signed with western powers over the last three hundred years has not been particularly positive, starting with "unequal treaties" arising from the Opium Wars of the 19<sup>th</sup> century. This leads China to view the WTO from a jaded perspective (Hobbs and Kerr, 2000). One cannot expect China to voluntarily play by the rules, but rather to attempt to circumvent them when it does not suit China's interests.

Chinese officials now say that they have run out of easy things to reform in their economic and social system. In order to maintain the dynamic growth that has contented its citizens for the last twenty-five years, the government realizes they must continue to open trade (The Economist, 2000). Beyond the constraints placed on China's willingness to open its economy by its development orientation, the government of China also faces strong, often regional, demands for protectionism. They have attempted a very delicate balancing act between opening trade and reaping the economic benefits and protecting

certain local industries. Some of the contradictions in trade policy and regulations are caused by the trade offs between these two priorities (Canadian Trade Commissioner Service, 2002).

#### *The Legal Regime for Imports in China*

China has made sweeping changes in its regulations and trade practices in order to open the Chinese market up to more international competition. China has traditionally used tariff and non-tariff measures to regulate its imports. Tax measures included value added taxes and consumption taxes as well as tariffs. Non-tariff measures include import licenses, import quotas control, restricted import lists, etc. In order to import, specific documentation is needed and the Chinese importers are generally responsible for providing this paper trail. Required documentation includes bills of lading, invoices, shipping lists, sales contracts, an import quota certificate for general commodities (where applicable), import licenses (where applicable), inspection certificates, insurance policies and customs declaration forms (Hong Kong Trade Development Council, 2000).

Before accession to the WTO, *special economic zones* proved advantageous for exporters of certain goods. The role of special economic zones, however, has changed dramatically since accession. There were four zones established in 1980 followed by one in 1988. These areas were designed to serve as windows for economic exchange between China and the rest of the world, and as a testing ground for experiments in economic reform. The Chinese government encouraged the use of the zones by building the required infrastructure and extending preferential measures for income tax, imports of raw materials and the introduction of foreign capital. These zones must now play a different role. Some of the special treatment extended to special economic zones had to

be withdrawn in order to fulfill WTO obligations such as the principle of Non-Discrimination. Further, many of the investment and trade friendly aspects of the zones that were still legal were laterally extended to everywhere in China once the wider economy was liberalized, in part through membership in the WTO. The zones still have an important role in the Chinese economy because they are now some of the most technologically and industrially advanced areas of the country. The zones also have the infrastructure to accommodate foreign investors, especially in biotechnology (Kwan, 2002).

Recent changes to the regulatory framework regarding biotechnology have become contentious trade issues. These regulations, ostensibly designed to deal with safety issues, were first promulgated in 1993. The State Science and Technology Commission of China, the Ministry of Agriculture, and the Ministry of Health, all issued regulations regarding biosafety matters (Wang, 2002). These regulations were modified, clarified and enhanced in 2002 when the Ministry of Agriculture issued three documents for managing biosafety, the Biosafety Evaluation Regulation for Agricultural GMOs, Import Regulation for Agricultural GMOs, and Labelling Regulation for Agricultural GMOs (Chen and Qu, 2002). The effects of the Biosafety Evaluation Regulation was discussed above and applies to all products that will be produced in China, including imports of intermediate goods containing GM material. If imports that will be used in the production chain are deemed as having a moderately high degree of risk, the restrictions that the product will face will be quite stringent (Cheng and Peng, 2002). These import regulations have had, and will continue to have, the largest effect on the trade of biotechnology products. These new regulations have been met with strong opposition

from China's trading partners, especially the US, who view them as protectionist rather than science-based. In addition to being coupled with the Labelling Regulation, these regulations require companies exporting products to China to apply for safety certificates stating that their products are harmless to humans, animals and the environment. It has been estimated that it will take at least 270 days, in addition to any delays that may be caused by having to wait for the crops to be grown for evaluation purposes (Ohio Integrated Pest Management, 2002).

The final component of the biosafety management regime in China is mandatory labelling at all levels of production and consumption of genetically modified materials. All products containing transgenic material, such as seeds, animal feed and food products, should have been labelled no later than July 2002. Companies that fail to comply with the labelling system risk having their sales revenue from GM products confiscated or face a fine of between 10,000 Yuan (US \$ 1,200) and 50,000 Yuan (US \$6,000) (*GENET News*, August 4, 2003). As almost no countries have an effective and cheap identity preservation system that can ensure that their products have never been in contact with GM material, many firms wishing to export into China could experience problems in certifying GM material for labelling purposes (Hobbs, 2001).

#### *The Reality of the International Trade Environment in China*

As in most jurisdictions that have set rules, there is some discrepancy between the formal rules and procedures and the actual application or bending of those rules in China. The most glaring example of this is how China approaches the new safety regulations on GMOs. As mentioned above, China enacted strict regulations on imports of GM products. There was a considerable backlash when the regulations were put in place as

exporters expressed concerns with the amount of time required to obtain a safety certificate and the costs that would be imposed on them due to the uncertainty caused by these regulations (Gale et al., 2002). As a result, China relented and decided to implement an interim system with far less strict rules for products of biotechnology that initially was to end on December 20, 2002. China then extended these conditions to September 20, 2003 as most firms had still not had enough time to comply with the new regulations (*Inside US Trade*, February 21, 2003). This deadline has once again been extended to April 2004 as China is still not ready to issue permanent safety certificates (*Inside US Trade*, July 18, 2003).

There has also been a considerable discrepancy between labelling regulations and actual practices. One year after all products containing GM material were supposed to be labelled, almost none had been and punishment for non-compliance has been almost non-existent (*GENET News*, August 4, 2003).

#### *Formal Complaints Brought Against China*

Some of the China's trading practices have developed into formal trade complaints, mostly from the US. The three main areas of disputes relating to biotechnology products and trade have been the protection of intellectual property, GMO import safety regulations and transparency in regulations.

After the June 6, 2001 announcement that China would be imposing new regulations on genetically modified organisms, US producers were perturbed by not only the "harsh news" of the new safety measures but also China's failure to notify producers exactly what those regulations were. U.S. Ambassador to China Clark Randt wrote to Vice-Premier Wen Jiabao stating that "We know from the U.S. industry that sales of U.S.

soybean have already been affected by the uncertainty that the new biotechnology regulation has created.” (*Inside US Trade*, August 24, 2001 p.22). China further infuriated US producers when on September 27, 2001 it announced a stepping up of requirements for documentation, testing and inspection of soybean shipments. This decision tied up shipments for weeks at Chinese ports. When US negotiators tried to raise the issue, Chinese quarantine officials, in essence, denied that they had instituted new measures or that trade was being deterred (*Inside US Trade*, October 19, 2001). While producers are relieved that China did not close its borders to biotechnology products while the safety regulations were being developed, the lack of information and the uncertainty that the “information gap” caused resulted in hundreds of millions of dollars in lost trade (Letter to the President of the United States, 2002).

One of the common characteristics of the trade complaints that are made, whether they relate to intellectual property laws, import safety regulations, tariff rate quotas, or any other issue, is that the Chinese government fails to give proper notice, fails to clarify important specifics or leaves ambiguities in the regulations. For example, the plans for the strict new import regulations on biotechnology trade were announced in June of 2001 but were not published for over six months. Once the regulations were published, important specific regulatory limits and procedures were not clarified (*Inside US Trade*, October 19, 2001). This lack of transparency does not comply with WTO principles and has become a trade irritant.

### **China’s Compatibility with the WTO**

Since China’s accession to the WTO in December, 2001, there has been a period of disequilibrium as countries, including China, adjust to the realities of this large economy

being formally integrated into the international trade economy. Although China's trade has not been free of conflict, the General Council of the WTO in its review of accession states, "[we] are satisfied with the improvements China has made to its trading standards during its first year as a WTO member" (China Central Television, 2003 p.1). Sixteen committees reviewed different aspects of the commitments China made and how they have lived up to those commitments. These committees reported that China has kept their word in reducing barriers for international access to their markets. The high praise has been coupled with "instructive advice" in order to help China continue to reform (China Central Television, 2003).

While the international community is quite happy with China's general progress, it is obvious from the complaints that have been made that there are still problems that need to be addressed. One of the key problems is with transparency of regulations, a key WTO principle. Questions have been raised by foreign producers, industry groups and sympathetic politicians who contend that China's GM import regulations do not comply with the WTO as they are not based on scientific criteria and that they are applying more stringent regulations on importers than on China's domestic producers (*Inside US Trade*, October 19, 2001). As suggested above, China has also enacted legislation that prevents foreign firms from investing in genetically modified seed-development. This may violate the spirit of WTO commitments to allow foreign investment and market involvement, if not the text of the agreements (Dow Jones Newswire, 2002).

### **Future Prospects for Chinese Biotechnology Trade**

As shown by the evidence above, China will play an important role in international biotechnology trade, but it will not be without controversy or conflict. The Chinese

government continues to invest heavily in biotechnology development and if they are going to be successful, they must secure international markets for their products. One necessary component of successful trade relationships will include allowing biotechnology products, such as GMOs, into the Chinese market as a sign of goodwill. The new safety regulations that China has put in place are clearly a barrier to trade, whether intended or not. The Chinese government has proved, however, that they are willing to compromise to accommodate the needs of foreign producers and to avoid disrupting trade beyond what is absolutely necessary.

Long term acceptance of biotechnology products in China, both domestic and foreign, has still not been determined. No one knows (likely including the government itself) what the next move will be in terms of regulations for products such as GMOs. China's government needs to take a firm stand rather than trying to sit on the fence. If they decide to support it wholeheartedly, biotechnology producers, such as the US, will become strong international allies. If, on the other hand, China decides that the health and environmental risks are too high and put stringent safety regulations in place, not only will it serve as a significant trade barrier, the effect on their domestic industry will likely be detrimental.

If China chooses to embrace biotechnology, their head start in the market will prove to be an important advantage. China is already the fourth (albeit a distant fourth) largest grower of transgenic plants in the world. They certainly have the potential to at least retain their competitive advantage, if not increase it significantly. As mentioned earlier, China has some issues with compliance to the WTO that need to be resolved if they are to reap all the benefits of their commitments.

## **China's Intellectual Property Protection**

### *Introduction to Intellectual Property Rights and International Agreements*

Intellectual Property Rights (IPRs) are critical in a knowledge-based economy. When IPRs are enforced, they allow firms to acquire monopoly profits (albeit temporary) to recoup their investment. This provides more incentive for firms to invest in research and development and discover products and techniques that will prove beneficial to society. However, when these rights are not enforced, it is often much less costly to reverse engineer a product than to pay the monopoly price. This results in the copy-cat firm being able to sell at a lower price as it does not incur the research and development costs. As a result, there is no incentive to innovate and, eventually, there would be few innovations to copy (Boyd et al., 2003).

When the WTO was formed in 1994, it was comprised of three main agreements: the General Agreement on Tariffs and Trade (GATT) that governs trade of goods; the General Agreement on Trade of Services (GATS) that governs trade of services; and the Agreement on Trade Related Aspects of Intellectual Property (TRIPS) which governs protection of intellectual property rights across international borders. A unique feature of the WTO is that each acceding country must agree to comply with all three agreements in order to be accepted into the WTO. If a country fails to comply with TRIPS obligations, a country can retaliate through GATT or GATS measures. The TRIPS includes provisions regulating what must be protected, for how long it must be protected, regulations and enforcement standards and consequences if other provisions are not adhered to (La Croix, 1998).

### *China and IPR Enforcement*

China's track record in IPR enforcement and copyright infringement presents a dismal picture. In 2001, it was estimated that roughly 95 percent of all software used in China was pirated. Although computer technology represents the worst area of pirate activity, 40 percent of shampoos that claim to be Proctor and Gamble and 60 percent of "Honda" motorbikes in China are actually fakes (The Economist, 2001b). There have been numerous firms in China that produce pirated material such as compact discs, motion pictures, computer game cartridges and textile designs (*Inside US Trade*, February 23, 1996). The problem in China, as in most developing nations, is not just lack of regulations ensuring intellectual property (IP) protection but also (and more importantly) lack of enforcement of these rules. Even when IPRs are enforced, the punishment for infringements are so small pirates simply consider them a cost of doing business (International AntiCounterfeiting Coalition, 2002). Other problems include lack of transparency in IP laws, lack of coordination between government agencies, local protectionism and corruption and lack of proper training for officials (USTR, 2003b).

### *IP Protection and Agricultural Biotechnology in China*

Agricultural biotechnology development in China has come from two main sources: (1) the Chinese Academy of Agricultural Sciences (CAAS) and; (2) technology transfers from companies based in industrialized nations. Some of these companies include Pioneer, Pacific Seeds, Monsanto and Delta and Pineland (Kowalski, 2003). The CAAS' mandate is to "[serve] nation-wide agricultural and rural development and [empower] farmers with science and technology" (Chinese Academy of Agricultural Sciences, 2004 p.1). As a result, the CAAS is much less concerned with capturing returns to the

investments they have made in research, provided the research has helped solve problems deemed important by the Chinese government. However, private companies require a competitive return on their investment in research or will turn their attention (and money) to more profitable endeavours (Boyd et al. 2003).

Similar to the general Chinese economy, agricultural biotechnology products have experienced weak IPR enforcement. In a study completed in 1999, it was found that Monsanto's 33B variety of Bt cotton has been widely distributed illegally. The Chinese company Ji Dai was the only company licensed to distribute 33B. However, all of the 33B grown in Shandong province, which amounted to over a third of the cotton produced in the province in 1999 and about one third of the 33B grown in Hebei province, which amounted to about twenty to twenty-five percent of all cotton grown in Hebei was not purchased from Ji Dai (Pray et al. 2001). The majority of the illegal seed was farmer-saved but some (mostly in the Shandong province) may be counterfeit. The result was that Monsanto earned only small returns in relation to the benefits achieved from using Bt cotton. Pray et al. 2001 estimate that Monsanto earned about 16 million RMB (1.93 million US\$) or less than 2.4 percent of the total benefits derived from using their variety of Bt cotton.

#### *Chinese Philosophy on IP Protection*

As the Chinese market has grown and matured, so have Chinese views on IP protection. When China was in its earliest developmental stages, IPRs were largely perceived as a mechanism to take from the poor and give to the rich – monopoly prices exploited poor people or farmers that had to purchase these goods. In the era of unreformed communism, private property rights in intellectual property were not

recognised for ideological reasons. In the early period of reform, China failed to see any benefits they could gain by enforcing almost entirely foreign held IP. For example, China's population is very poor and most would not be able to afford medical treatment for hepatitis if they enforced the IPRs that existed on those treatments (The Economist, 2001c). As China had almost no intellectual property of its own, the only motivation for enforcement was international pressure, which very quickly took a backseat to local concerns. This began to change as China began developing their own IP and needed to comply with TRIPS to be granted accession to the WTO. The Chinese government states, "China has every reason to provide a high level of IPR protection since we have a growing number of local inventions and famous trademarks to be protected" (WTO, 2002 p.7). They also realize that "the intellectual property protection system plays an important role in promoting scientific and technological innovation, cultural prosperity and economic development" (WTO, 2002 p.2). China has been promulgating new laws for the last two decades reflecting this paradigm shift.

China will now grant IP protection once specific criteria are met. A patent will be granted in China only if the invention shows novelty and inventiveness and has practical or industrial application. In order to be novel, an application must be new and not already in the public domain. Article 22.2 of the Patent Law of the People's Republic of China states:

Novelty means that, before the date of filing, no identical invention or utility model has been publicly disclosed in publication in the country or abroad or has been publicly used or made known to the public by any other means in the country, nor has any other person filed previously with the Patent Administration Department Under the State Council and application which describe the identical invention or utility model and was published after the said date of filing (WTO, 2002, p.32).

Inventiveness requires that the invention should not be obvious to a person that is skilled in the art and should have substantive features and show notable progress in comparison to existing products. In order to have practical or industrial application, the product must not only be capable of being manufactured and used but must also be capable of producing positive effects according to social, economic or technical standards (Bachner, 2002). In addition to these requirements, China states that, “No patent right shall be granted for any invention-creation that is contrary to the laws of the State or social morality or that is detrimental to the public interest” (WTO, 2002, p.32). This allows China to have considerable leeway in determining whether to grant a patent, as in certain cases it could easily be argued that doing so was “detrimental to the public interest”.

China, along with most other nations, cannot look to tradition when it comes to developing a national position in regards to whether or not living organisms should be granted IPRs. Shortly after China acceded to the Food and Agricultural Organization’s International Undertaking on Plant Genetic Resources (UPOV) Act, the State Council established new rules in respect to plant IP. These rules can prevent others from producing or selling any of the protected breeding material and from using the protected breed repeatedly. These laws, however, remain largely untested in the Chinese courts and only time will tell how strong this protection really is (Bachner, 2002). Products of biotechnology are eligible for patents assuming they meet the requirements of novelty, inventiveness and practical applicability.

### **Intellectual Property Legal Regime in China**

Since the 1980s, China has continued to enact new laws and build upon old laws in order to improve their IP protection. The first milestone in the construction of a modern IPR

protection system in China was the promulgation of the Chinese Trademark Law in 1982. This was followed by the Chinese Patent Law in 1984. These two sets of rules provided the backdrop for future development. In 1986, the General Principles of Civil Law were ratified. This established IPR as a civil right of natural and legal persons in the basic civil law. The Chinese Copyright Law was put in place in 1990 and an accessory to that law, the Regulations for the Protection of Computer Software followed in 1991. The Provisions on the Implementation of the International Copyright Treaty were passed in 1992 clarifying the rights of foreign copyright holders. Amendments in 1992 to the patent law extended protection to products of chemicals and lengthened protection time of patents and designs to 20 years and 10 years respectively. An important step was made in 1994 when the Decisions on Penalizing the Crimes of Infringing Copyright made IP infringement a criminal offence. The Trademark laws were amended again in 1993 and 1995 to provide protection for service trademarks. The Provisions of Penalizing the Crimes of Counterfeiting Registered Trademarks in 1993 strengthened the protection of registered trademarks. Infringement of IPR was declared an unfair competition method when the Law of Prevention of Unfair Competition came into force in 1993. In 1995, the Regulations on IPR Border Protection was issued and an additional provision, the Regulations on Protection of Plant Varieties was put in place in 1997 (APEC, 1997). As China attempted to bring their regulations into full compliance with TRIPS, an “across the board amendment” initiative was undertaken (WTO, 2002 p.2). This overhaul covered almost every major IPR related law and regulation that existed in China. China believes that they have now undertaken all of the changes required to be fully compliant

with TRIPS. However, it is quite likely that China will have to continue modifying their laws as deficiencies become apparent.

Many of these regulatory changes were a direct result of international agreements that China had signed. In 1980, China became a member of the World Intellectual Property Organization. In 1985, China became a member of the Paris Convention for the Protection of Industrial Property and in 1989 became a member of the Madrid Agreement Concerning the International Deposit of Industrial Designs. In 1992, China became a member of the Bern Convention on the Protection of Literary and Artistic Works and in the following year, became a member of the Convention for the Protection of Producers of Phonograms Against the Unauthorized Duplication of Their Phonograms. In 1994, China became a member of Patent Cooperation Treaty and the Nice Agreement concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks. China joined the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure and applied for membership to the Protocols of Madrid Agreement Concerning the International Deposit of Industrial Designs in 1995. In 1996, China became a member of Logano Agreement on Establishing an International Classification for Industrial Designs. In 1997, China joined the Strasbourg Agreement Concerning the International Patent Classification (APEC, 1997). In July of 2001, it passed new laws in order to bring their system into compliance with TRIPS for China's accession to the WTO (The Economist, 2001b). China is also considering signing on to several of the new treaties being proposed by the World Intellectual Property Organization such as the Internet Treaty (*Inside US Trade*, February 28, 2003), the Copyright Treaty and the Performances and

Phonograms Treaty (WTO, 2002). In addition to these multilateral agreements, China has also entered into bilateral cooperation with a number of countries such as the EU, in which China receives training assistance in return for improving local enforcement (WTO, 2002).

### *The Reality of Intellectual Property Protection in China*

While China has worked hard to bring their intellectual property laws up to international standards, piracy is still rampant in China. As mentioned earlier, while many laws exist, in countless cases these laws are not enforced. The failure to enforce is not only the result of opportunistic behaviour by corrupt law enforcement officials or politicians but also because of a fundamental lack of a proper enforcement framework. One of the most pressing issues is the lack of properly trained law enforcement officers. In the past, there has simply not been sufficient resources allocated to ensuring everyone from the police to supreme court judges are knowledgeable enough to properly handle IP infringement cases (*Inside US Trade*, February 23, 1996). This is not to imply, however, that opportunistic behaviour does not play an important role in the absence of enforcement. The Chinese system is extremely complex with many overlapping jurisdictions. This has led to a system that can be manipulated by individuals in places of authority. It is all part of the wider problem of the corruption associated with a “licensing economy” (Kerr and MacKay, 1997). While the legal and cultural structure that exists today still leaves a great deal of room for improvement, China is officially attempting to comply with both international and domestic pressure to make the necessary changes (The Economist, 2001c).

Formal complaints regarding China's IP protection have existed almost since China decided to open its economy to foreign firms. For example, in February of 1996 U.S. copyright industries called on the Clinton Administration to impose trade sanctions against China after they failed to comply with an agreement made in February of 1995 (*Inside US Trade*, February 23, 1996). Since China's accession to WTO, most governments are choosing to not file formal complaints with international organizations such as the WTO, choosing rather to take a diplomatic approach. These countries have decided to give China a small grace period in order allow it to voluntarily enact and enforce IP laws. Also, due to the short time period in which to observe if China is actually upholding TRIPS, countries have difficulty knowing if China is actually breaking their international commitments. This has resulted in the US government choosing to address these issues privately with Chinese diplomats (*Inside US Trade*, February 28, 2003). However, senior US officials have stated that intellectual property rights violations represented the most likely targets for US challenges against China at the World Trade Organization (*Inside US Trade*, October 31, 2003)

#### *China's Compliance with TRIPS*

There have been many questions raised internationally as to whether or not China is in compliance with TRIPS. In a WTO review of China's legislation, the European Union and its Member States stated that they believed China's legislation was not in compliance and asked when changes could be expected. China responded by stating that their regulations have no contradictions with the TRIPS articles and no revisions were necessary. Some of the issues that many countries have expressed concerns over are national treatment of foreigners with patents in China, the time period which it takes to

receive a patent, the widespread localism that impedes quick and accurate intellectual property right enforcement, the lack explicit regulations to empower a court to destroy infringing goods, lack of proper punishment to create an effective deterrence system and the strong burden of proof that befalls the right holders when initiating a case (WTO, 2002). US Assistant Secretary of Commerce for Market Access and Compliance William Lash stated that “China deserved a grade of somewhere between a ‘C’ and a ‘D+’ for its efforts in [intellectual property rights]” and the only reason he spared China an ‘F’ was because some Chinese official are interested in making improvements (*Inside US Trade*, November 21, 2003).

Although China has continued to bring its legislation closer to international standards, one of the most common complaints is that they are still failing to comply with one of the fundamental obligations of TRIPS. The TRIPS requires countries to “implement effective enforcement procedures and provide remedies that have a deterrent effect” (USTR, 2003b p.1). While China has some mechanisms in place to deal with repeat offenders, the thresholds for triggering these mechanism are very high and likely to be effective only in the most extreme cases. Criminal charges for patent infringement can only be laid if:

the sum of the distribution is large, the amount of illegal gains is relatively huge, the loss caused by the offence of another person who enjoys the rights is heavy, the counterfeiting is comparatively frequent, and the time of the infringement is long... (WTO, 2002 p.38).

In civil cases, the court may order the pirates to cease infringement, extend an apology, eliminate the ill effects and compensate the right holder for losses. However, in most cases, the punishments are far below the level needed to significantly discourage piracy. Many countries also believe that in addition to needing stronger penalties and lower

thresholds for their application, China needs to attempt to prosecute a much greater percentage of offenders (WTO, 2002). They believe this would be possible if China increased transparency, coordination among different agencies and training for officials and decreased the potential for local protectionism (USTR, 2003b).

China is very aware of what it must do in order to comply with TRIPS as they have already promised to undertake the majority of the necessary reforms. While it has only been a short time since China's WTO accession, it is becoming apparent that significant problems still exist. China has painstakingly revised their legislation and now one of the most pressing questions is whether or not they will begin effectively enforcing it.

#### *Future Prospects of China's Intellectual Property Laws*

The future of China's intellectual property laws is opaque and only time will tell if they will slip back into their intellectual property free-for-all system or whether a system that protects IP and encourages research and development of new products and production techniques will evolve. There are two things that will prove to be strong incentives for China to move towards a more stringent system: (1) for the first time in recent history, China is beginning to have significant IP of its own that it wants to protect and; (2) China is trying to build a much stronger trade relationships with countries such as the US, Japan, Australia and the EU (all countries that place great value on IPRs) and will not want IPRs to serve as a significant trade irritant.

If China does not continue to upgrade their IPRs, the effect on the Chinese knowledge-based industries will be detrimental as foreign companies hesitate or refuse to sell or produce their goods in China for fear of widespread piracy. China must be willing to take a hard line approach when dealing with offenders in order to establish a strong

system of deterrence. If they are able to do this and curb counterfeiting in China, their domestic knowledge-based industries will have a much better chance to flourish and international investors in China will not feel threatened by poor IPRs. If they cannot, then China will be limited to second-tier technology which would fall short of global standards and relatively obsolete. This could effectively delay or prevent Chinese farmers from being able to reap the benefits from the latest advances in agricultural biotechnology. Furthermore, proper enforcement of IPRs would help to foster local, private research in biotechnology. More Chinese companies would be willing to invest in research and development of agricultural biotechnology products if they believed their work would be protected from copies, thus increasing the chances of recouping their investment (Kowalski, 2003). The government appears to have realized that the long-term benefits of good IP protection will far outweigh the short run costs.

### **Conclusions Regarding China's Biotechnology Industry and Trade Issues**

This paper has examined China's biotechnology industry, market structure, legislation, international treaties and obligations, trade policies and issues affecting Chinese trade all in an attempt to answer one fundamental question: Will China be integrated in the world biotechnology industry? It is apparent that China has considerable potential to play an important role in the development of this international industry but they must continue to make a conscious effort to avoid pitfalls.

China has gone down an extremely long road taking it from a segregated and poor country to having the potential to be the second largest economy of the world. They have made this journey, for the most part, by making promises about how things will change and then making token changes. China's promises have allowed them accession to the

WTO but those promises must now be acted upon. It is apparent that China still has a considerable distance to travel before it is in exact (or even significantly closer) compliance with their WTO accession agreement.

China's future in the biotechnology industry is still a blank page in the history books, waiting to be written. It is certainly in a position to benefit from the opportunities that biotechnology may provide such as increased food security, domestic production and rural incomes, decrease environmental degradation and the economic, social and political benefits that would accompany increased international trade. While China has laid the foundation as an important player in the industry, they have also began to lay the foundation for stifling their carefully constructed industry by imposing drastic safety regulations on GMOs. The government needs to carefully examine what these arguably non-science based rules could do not only to the domestic biotechnology industry but to the Chinese economy as a whole. China is now in the unique position of being ready to go in whatever direction it chooses, it just must choose what direction that is.

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## Endnotes

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<sup>1</sup> A fragrant herb used in incense, aromatherapy oils, soaps and perfumes.

<sup>2</sup> Often public funds will only go to areas in which the government feels will benefit society as a whole or help address serious societal problems. Funds are not usually directed toward areas that would generate the largest profits. It also limits risk taking which can, in turn, lead to considerable forgone benefits for society.