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INTELLECTUAL PROPERTY RIGHTS AND THE PUBLIC SECTOR: WHY COMPULSORY LICENSING OF PROTECTED TECHNOLOGIES CRITICAL FOR FOOD SECURITY MIGHT JUST WORK IN CHINA

Gregory C. Ellis[†]

Abstract: The majority of people in the developed world have the luxury of never having to address food shortages and malnutrition. In developing countries, however, ensuring food security presents greater challenges. Agricultural biotechnology has the potential to alleviate many of the food crises occurring in developing countries. Unlike private sector corporations, public sector entities are creating genetically modified (“GM”) crops to ensure food security. However, the intellectual property rights (“IPRs”) to the many technologies required to create a single GM crop are often fragmented across the private and public sectors. Fragmentation of IPRs creates a “patent thicket” that increases the challenges of developing GM crops that are not restrained by freedom to operate complications.

China has a successful agricultural biotechnology industry that is almost entirely public sector. Recently, China strengthened its intellectual property (“IP”) laws as a result of its accession to the World Trade Organization (“WTO”). Despite the beneficial effects of harmonizing IP laws among WTO member states, there exists a negative consequence of IP globalization as it pertains to China’s public sector-driven agricultural biotechnology industry. Stronger IP laws and enforcement will create an environment more favorable to the interests of foreign private sector entities. Any subsequent introduction of technologies used to create GM crops will result in the protection of such technologies under Chinese law, but without open availability under most circumstances. To reduce the potential frustration of its public sector, China should declare potential food shortages a national emergency. In doing so, China may require compulsory licensing of the technologies necessary to create GM crops essential for food security without violating its WTO obligations. Because the compulsory licenses would be granted only for selected technologies used to create GM crops, such licensing would reduce the negative effects of IPRs fragmentation without raising substantial concerns of compromised innovation resulting from parallel importation.

I. INTRODUCTION

The developing world has over 800 million undernourished people.¹ Nearly eleven million children die each year, with more than half of these deaths resulting from hunger and malnutrition.² The vast majority of deaths attributable to hunger and malnutrition occur in developing countries.³

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¹ FOOD AND AGRICULTURE ORGANIZATION, UNITED NATIONS, THE STATE OF FOOD INSECURITY IN THE WORLD 2005, 30 (2005).

² *Id.* at 18.

³ *Id.*

Unfortunately, although there is currently enough food to feed the world, it is unequally distributed, as 650 million of the poorest people live where agricultural potential is substandard.⁴ Additional methods of ensuring food security to prevent hunger and malnutrition beyond the access to food paradigm must, therefore, be considered.⁵ Food security “exists when all people, at all times, have physical and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life.”⁶

Agricultural biotechnology is one promising device heralded to be valuable in ensuring food security.⁷ Agricultural biotechnology research intended to enhance food security in developing countries includes creating GM crops that reduce the use of pesticides, improve stress tolerance, and provide better product quality and increased nutritional value.⁸

The use of agricultural biotechnology to create GM crops is a contentious issue. Opponents of this technology claim that GM crops are “inherently dangerous,”⁹ and that the scientific understanding of the impact that GM crops have on the environment and human health is inadequate.¹⁰ Some of these concerns are legitimate. For example, in September 2000, trace amounts of a transgenically expressed protein known as Cry9C, which is approved for animal but not human use, was found in Kraft Taco shells in the United States.¹¹ These concerns are especially important in developing countries that are beginning to approve and commercialize GM crops but do not yet have comprehensive regulatory provisions in place.¹²

⁴ Gordon Conway & Gary Toenniessen, *Feeding the World in the Twenty-First Century*, 402 NATURE C55, C55 (1999).

⁵ *Id.*

⁶ Robert H. Trudell, *Food Security Emergencies and the Power of Eminent Domain: A Domestic Legal Tool To Treat A Global Problem*, 33 SYRACUSE J. INT'L L. & COM. 277, 277-78 (2005).

⁷ Barun Mitra et al., *31 Critical Questions In Agricultural Biotechnology*, AGBIOWORLD, <http://www.agbioworld.org/biotech-info/articles/agbio-articles/critical.html> (last visited Nov. 24, 2006).

⁸ Joel I. Cohen, *Poorer Nations Turn to Publicly Developed GM Crops*, 23 NATURE BIOTECHNOLOGY 27, 31-32 (2005).

⁹ See, e.g., Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L.J. 47, 57 (2001).

¹⁰ See Greenpeace International, *Say No to Genetic Engineering*, <http://www.greenpeace.org/international/campaigns/genetic-engineering/> (last visited Nov. 14, 2006).

¹¹ Linda Beebe, Note, *In re Starlink Corn: The Link Between Genetically Damaged Crops and an Inadequate Regulatory Frame Work for Biotechnology*, 28 WM. & MARY ENVTL. L. & POL'Y REV. 511, 514-17 (2004).

¹² See generally Christina L. Richmond, *Genetically Modified Crops in the Philippines: Can Existing Biosafety Regulations Adequately Protect the Environment?*, 15 PAC.RIM L. & POL'Y J. 569 (2006) (discussing how the Philippines' existing regulations are inadequate to address the environmental impacts of agricultural biotechnology).

Despite such criticisms, proponents of agricultural biotechnology argue that its benefits far outweigh its potential risks, and that the risks that do exist are not inherent properties of the technology. According to the Declaration of Support for Agricultural Biotechnology, signed by over 3400 international scientists, including twenty-five Nobel Prize Laureates,¹³ the technologies utilized to create GM crops can safely and substantially enhance efforts to ensure food security.¹⁴ Dr. Patrick Moore, a co-founder and former leader of Greenpeace who has since signed the Declaration, stated that “the campaign of fear now being waged against genetic modification is based largely on fantasy and a complete lack of respect for science and logic.”¹⁵

Critics further assert that agricultural biotechnology corporations exploit the hungry in developing countries for “commercial opportunity,” some going as far as labeling this activity as criminal.¹⁶ This claim, however, fails to acknowledge that while the private sector focuses mostly on crops with large markets, the nonprofit public sector provides the developing world with subsistence crops to ensure food security, despite their lack of high commercial value.¹⁷

China provides a model for public sector success with respect to agricultural biotechnology, with almost all research and development in this field being conducted by the public sector.¹⁸ What makes China unique in comparison to other developing countries’ public sectors is its strong scientific infrastructure.¹⁹ This infrastructure allows Chinese scientists involved in agricultural research to successfully generate “an impressive array of new technologies.”²⁰ Furthermore, China’s agricultural biotechnology industry focuses on providing food security, as “the foods

¹³ *Scientists In Support of Agricultural Biotechnology*, AGBIOWORLD, <http://www.agbioworld.org/declaration/index.html> (last visited Nov. 23, 2006).

¹⁴ *Petition In Support of Agricultural Biotechnology*, AGBIOWORLD, <http://www.agbioworld.org/declaration/petition/petition.php> (last visited Nov. 23, 2006).

¹⁵ C.S. Prakash, *Greenpeace Founder Supports Biotechnology*, AGBIOWORLD, Mar. 6, 2001, <http://www.agbioworld.org/biotech-info/pr/moore.html>.

¹⁶ Reece Walters, *Crime, Bio-Agriculture and the Exploitation of Hunger*, 46 BRIT. J. CRIMINOLOGY 26, 26 (2006).

¹⁷ Richard C. Atkinson et al., *Public Sector Collaboration for Agricultural IP Management*, 301 SCIENCE 174, 174 (2003); Eran Binenbaum et al., *South-North Trade, Intellectual Property Jurisdiction, and Freedom to Operate in Agricultural Research on Staple Crops*, 51 ECON. DEV. & CULTURAL CHANGE 309, 309-10 (2003).

¹⁸ Fred Gale et al., *Is Biotechnology in China’s Future?*, in CHINA’S FOOD AND AGRICULTURE: ISSUES FOR THE 21ST CENTURY 34, 34 (2002), available at <http://www.ers.usda.gov/publications/aib775/aib775m.pdf>; Jikun Huang et al., *Plant Biotechnology in China*, 295 SCIENCE 674, 674 (2002).

¹⁹ Huang et al., *supra* note 18, at 674.

²⁰ *Id.*

being modified [in China] reflect the concern that current food production will not fill the hungry mouths of its future population.”²¹

Agricultural biotechnology research poses unique IP issues that are particularly pronounced for the public sector.²² These IP issues lie not with the GM crops themselves, but with the technologies required to create them.²³ Developing a single GM crop requires numerous technologies.²⁴ Innovators usually protect these technologies via IPRs, most notably patents,²⁵ which are often held by dissimilar owners.²⁶ IPRs fragmentation develops when no single IPRs owner has complete ownership of all the technologies required to create a GM crop.²⁷ In such a situation, all that is required to hinder the development of an important GM crop is for a single IPRs holder to refuse to license the technology.²⁸ However, as agricultural biotechnology research and development in China is driven by the public sector, fragmentation of IPRs among the public and private sectors has been largely nonexistent.

On December 11, 2001, China became the 143rd member of the WTO.²⁹ As a result, China has been strengthening its intellectual property laws as mandated by the Trade Related Aspects of Intellectual Property Rights (“TRIPS”) agreement,³⁰ applicable to all WTO members.³¹ The main objectives of TRIPS are to improve and harmonize IP protection and to

²¹ Tom Clarke, *China Leads GM Revolution*, NATURE, Jan. 25, 2002, <http://www.nature.com/news/2002/020121/full/020121-13.html> (last visited Apr. 5, 2007).

²² Conway and Toenniessen, *supra* note 4, at C57-C58. See generally Atkinson et al., *supra* note 17 (discusses the IP complications that exist when a single GM crop requires numerous patented technologies that are owned by multiple entities); Gregory D. Graff et al., *The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology*, 21 NATURE BIOTECHNOLOGY 989 (2003) (discusses the difficulties public sector agricultural biotechnology entities face when private sector entities hold IPRs to technologies required by the public sector).

²³ Atkinson et al., *supra* note 17, at 174; Graff et al., *supra* note 22, at 992-994.

²⁴ Atkinson et al., *supra* note 17, at 174.

²⁵ Although this comment deals with IP issues relating mostly to patents, this comment will broadly refer to any type of IP protection as IPRs, so as to not inadvertently exclude other types of IP protection other than patents that might be relevant to issues discussed in this comment.

²⁶ Atkinson et al., *supra* note 17, at 174.

²⁷ *Id.*; see also Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698 (1998).

²⁸ Graff et al., *supra* note 22, at 989.

²⁹ U.S. TRADE REPRESENTATIVE, 2004 REPORT TO CONGRESS ON CHINA’S WTO COMPLIANCE, 9 (2004); see also World Trade Organization, *Protocol on the Accession of the People’s Republic of China*, WT/L/432 (Nov. 23, 2001) (providing the terms of China’s accession agreement).

³⁰ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994 Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS]; *Id.* at 5.

³¹ *Id.* at art. 1; World Trade Organization, *Frequently Asked Questions About TRIPS in the WTO*, http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm#Who'sSigned (last visited Apr. 5, 2006).

introduce compulsion through enforceable sanctions.³² Although the advantages of IPRs harmonization might outweigh the disadvantages, this comment will address a unique and potentially negative effect resulting from the strengthening of IPRs in China.

The strengthening of IPRs in China will help to create an environment more favorable to the interests of the private sector's agricultural biotechnology interests. Consequently, the private sector's presence will likely increase in China. This will lead to the fragmentation of IPRs between China's public sector and the private sector entities interested in protecting their technologies for commercial purposes. Such a divide will frustrate China's efforts to ensure adequate food security.

This comment argues that, to prevent IPRs fragmentation, China should exercise its right under TRIPS to mandate compulsory licensing for protected technologies essential for food security. As compulsory licensing for pharmaceuticals is controversial due to concerns of parallel importing, those licenses should only be granted under exceptional circumstances. However, similar parallel importing concerns would be less substantial for agricultural biotechnologies in China because the same technologies may be used for other GM crops with significantly higher commercial value. As a result, compulsory licenses are more appropriate for agricultural biotechnologies important to the public sector than for pharmaceutical products. Part II of this comment describes the issues surrounding the public sector's efforts to develop GM crops for purposes of food security, as well as the current agricultural biotechnology environment in China. Part III discusses the recent strengthening of Chinese IP laws and enforcement. Part IV predicts the likelihood and subsequent consequences of an increased presence of foreign agricultural biotechnology companies in China. Finally, Part V argues that compulsory licensing of technologies essential for food security can proceed without violating TRIPS or compromising overall innovation within the agricultural biotechnology industry.

II. FRAGMENTED IPRs CREATE CHALLENGES FOR AGRICULTURAL BIOTECHNOLOGY'S PUBLIC SECTOR

In developing countries such as China, the public sector focuses its research on basic food staples important to local economies.³³ When the

³² JOHN REVESZ, PRODUCTIVITY COMMISSION, TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, PRODUCTIVITY COMMISSION STAFF RESEARCH PAPER, at xvi (1999), available at <http://www.pc.gov.au/research/staffres/trips/trips.pdf>.

³³ Cohen, *supra* note 8, at 31.

creation of a single GM crop requires multiple technologies, freedom to operate complications will result if the IPRs holders of such technologies prevent access to their technologies.

A. *The Public Sector in Developing Countries Anticipates Using Agricultural Biotechnology to Ensure Food Security*

Beginning in the 1960s, agricultural research aimed at increasing the overall food production in order to meet the demands of a rapidly growing population resulted in higher yielding varieties of rice, wheat, and maize.³⁴ Known as the Green Revolution, this campaign to increase food security helped reduce the total number of hungry persons by more than half.³⁵ Today however, over 800 million people are still undernourished,³⁶ and “the gains in food production provided by the Green Revolution have reached their ceiling while the world population continues to rise.”³⁷ By the year 2048, the world population will grow from six to nine billion.³⁸ Furthermore, global warming, deforestation, pollution, overgrazing, soil erosion, and urbanization will challenge the assurance of adequate food security.³⁹

Although the guarantee of food security will ultimately require multiple approaches, agricultural biotechnology provides a promising tool to combat hunger and malnutrition.⁴⁰ The proportion of the global area of GM crops grown in developing countries increased every year during the period from 1996 to 2005.⁴¹ Furthermore, the governments of developing countries in Asia appear to vigorously support agricultural biotechnology.⁴²

³⁴ Conway & Toenniessen, *supra* note 4, at C55.

³⁵ *Id.*

³⁶ FOOD AND AGRICULTURE ORGANIZATION, *supra* note 1, at 30.

³⁷ Conway & Toenniessen, *supra* note 4, at C55.

³⁸ U.S. CENSUS BUREAU, GLOBAL POPULATION AT A GLANCE: 2002 AND BEYOND (2004), available at <http://www.census.gov/prod/2004pubs/wp02-1.pdf>.

³⁹ ASIAN DEVELOPMENT BANK, AGRICULTURAL BIOTECHNOLOGY, POVERTY REDUCTION, AND FOOD SECURITY 4 (2001) (listing pollution, deforestation, and urbanization); Nsongurua J. Udombana, *How Should We Then Live? Globalization and the New Partnership For Africa's Development*, 20 B.U. INT'L L.J. 293, 317 (2002) (highlighting global warming); Indra K. Vasil, *Biotechnology and Food Security for the 21st Century: A Real-World Perspective*, 16 NATURE BIOTECHNOLOGY 399, 399 (1998) (citing pollution, overgrazing, and soil erosion); Lauren Sacks & Cynthia Rosenzweig, *Climate Change and Food Security*, CLIMATE.ORG, <http://www.climate.org/topics/agricul/index.shtml#warming> (last visited Jan. 28, 2007) (citing global warming).

⁴⁰ Conway & Toenniessen, *supra* note 4, at C55; Mitra et al., *supra* note 7.

⁴¹ CLIVE JAMES, INTERNATIONAL SERVICE FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2005, at 6 (2005).

⁴² Richmond, *supra* note 12, at 571; see also RAYMOND HOH, USDA FOREIGN AGRICULTURAL SERVICE GAIN REPORT, MALAYSIA BIOTECHNOLOGY ANNUAL 2006, at 6-7 (2006); NATIONAL CENTER FOR GENETIC ENGINEERING AND BIOTECHNOLOGY, NATIONAL SCIENCE AND TECHNOLOGY DEVELOPMENT AGENCY, THAILAND'S NATIONAL BIOTECHNOLOGY POLICY FRAMEWORK 2004-2009, at 1 (2005); Clarke, *supra* note 21.

Therefore, this comment will assume that agricultural biotechnology will continue to be a potential avenue for food security in developing Asian countries. The primary focus of this comment is not to discuss the benefits and risks of agricultural biotechnology, as exhaustive debates on this subject may be found elsewhere. Instead, this comment will focus on the IP-related issues complicating the efforts of China's public sector to create GM crops aimed at reducing hunger and malnutrition.

B. China's Thriving Agricultural Biotechnology Industry is Public Sector and Focuses on Food Security

China conducts more research on plant biotechnologies than any other country outside of North America⁴³ and accounts for over ten percent of all public sector expenditures on agricultural biotechnology research worldwide.⁴⁴ By acreage, China is the fifth largest producer of agricultural biotechnology crops in the world.⁴⁵ Furthermore, China's public sector is committed to developing GM crops that the developed world has largely ignored.⁴⁶ This contrasts sharply with the objectives of private sector entities that fail to focus on "crops that are important to the world's poor farmer."⁴⁷ Although China has limited commercial ambitions with respect to its agricultural biotechnology industry, the industry's primary focus lacks the commercial ambitions of other Asian countries. For example, Thailand has recently launched an aggressive agricultural biotechnology campaign in hopes that it will become known as "[t]he kitchen of the world."⁴⁸ This campaign exists as an effort to increase its export revenue.⁴⁹

The incentive to increase food security in China is profound, as approximately 142 million (eleven percent) of China's population is undernourished.⁵⁰ Although China has less than ten percent of the world's arable land, it feeds more than twenty percent of the world's population.⁵¹ With the predicted population increases, China will need to increase its food grain production by almost forty-five percent by 2020 to maintain its current

⁴³ Clarke, *supra* note 21.

⁴⁴ Huang et al., *supra* note 18 at 675.

⁴⁵ USDA FOREIGN AGRICULTURAL SERVICE, PEOPLES REPUBLIC OF CHINA AGRICULTURAL BIOTECHNOLOGY REPORT 2005, at 3.

⁴⁶ Huang et al., *supra* note 18 at 674.

⁴⁷ *Id.*

⁴⁸ NATIONAL CENTER FOR GENETIC ENGINEERING AND BIOTECHNOLOGY, *supra* note 42, at 6-9 (2005).

⁴⁹ *Id.*

⁵⁰ FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, *supra* note 1, at 30.

⁵¹ Huang et al., Agricultural Biotechnology Policy Processes in China 7 (2001), available at <http://www.ids.ac.uk/ids/KNOTS/PDFs/China.pdf>.

food supply.⁵² To reach this goal, China has been increasing its publicly funded research investments in agricultural biotechnology.⁵³ During the second half of the last decade, investment in agricultural biotechnology increased thirty percent per year,⁵⁴ and in 2004, China spent \$200 million on agricultural biotechnology research.⁵⁵

The success of China's agricultural biotechnology research efforts comes not only from the financial expenditures put forth by public investment, but also to its strong scientific infrastructure.⁵⁶ China employs over two thousand employees in agricultural biotechnology research alone.⁵⁷ As of 2001, China had close to 150 laboratories located in more than fifty research institutes and universities working on agricultural biotechnology.⁵⁸ The Chinese Academy of Sciences, the Chinese Academy of Agricultural Sciences, provincial academies of agricultural sciences, and general and agricultural universities carry out China's agricultural research.⁵⁹ Furthermore, the percentage of agricultural biotechnology scientists having Ph.D.s is expected to increase as the ability to conduct Ph.D. educational programs in biotechnology continues to strengthen.⁶⁰ These efforts have led to China's Ministry of Agriculture's approval of 585 GM plant experiments, including 154 environmental releases, as of 2003.⁶¹ China's identification of over 120 functional genes used in agricultural biotechnology research and development exemplifies the fruits of its strong scientific infrastructure.⁶²

⁵² *Id.* at 7-8.

⁵³ Jikun Huang & Qinfang Wang, *Agricultural Biotechnology Development and Policy in China*, 5 *AGBIOFORUM* 122, 131 (2002).

⁵⁴ *Id.*

⁵⁵ John D. Connor et al., *China's Regulation of Agricultural Biotechnology*, THE METROPOLITAN CORPORATE COUNSEL, Dec. 2006, <http://www.metrocorpocounsel.com/current.php?artType=view&EntryNo=5987> (last visited Apr. 5, 2007).

⁵⁶ Huang et al., *supra* note 18, at 675.

⁵⁷ *Id.*

⁵⁸ Huang & Wang, *supra* note 53, at 125.

⁵⁹ Carl E. Pray, *Public and Private Collaboration on Plant Biotechnology in China*, 2 *AGBIOFORUM* 48, 49 (1999).

⁶⁰ Huang et al., *Agricultural Biotechnology Research Indicators: China 8* (Center for Chinese Agricultural Policy, Chinese Academy of Sciences, Working Paper, Oct. 2001), available at <http://www.sciencemag.org/cgi/data/295/5555/674/DC1/4>.

⁶¹ Jia Hepeng, *China Intends to Push For GM Crop Studies*, CHINA DAILY, Feb. 14, 2006, http://www.chinadaily.com.cn/english/doc/2006-02/14/content_519960.htm (last visited Apr. 5, 2007).

⁶² Huang et al., *supra* note 60, at 25.

C. *Fragmentation of IPRs Creates Obstacles for Public Sector Entities Engaged in Agricultural Biotechnology Research*

The fragmentation of IPRs among multiple owners of the technologies used to create GM crops complicates public sector agricultural biotechnology research.⁶³ The creation of a single GM crop requires incremental improvements upon previously derived processes.⁶⁴ Many of the incremental improvements pertain to “enabling technologies,” processes that can be used to create a variety of different GM crops.⁶⁵ A process that improves the transfer of an exogenously expressed gene into a host plant is an example of such an enabling technology.⁶⁶ When commercial interests are at stake, however, proprietary owners of one or more of the enabling technologies required to develop a GM crop may be reluctant to provide access to the protected technologies.⁶⁷

Golden Rice, a GM crop, best exemplifies the complexity of the “patent thicket” created by IPRs fragmentation. Golden Rice is genetically modified to contain significantly elevated levels of vitamin A as a result of the transgenic expression of beta-carotene, a vitamin A precursor.⁶⁸ Chronic vitamin A deficiency affects between one and two hundred million children, resulting in permanent blindness for about 500,000 of these children each year.⁶⁹ Additionally, between one and three million children die annually of infections, which would have been preventable had the children acquired sufficient amounts of vitamin A.⁷⁰

Golden Rice exemplifies the benefits of GM crops that can compensate for nutritional deficiencies.⁷¹ The potential impact of Golden Rice, which is predicted to save almost 40,000 lives annually in the developing world, is astounding.⁷² The development of Golden Rice, however, required seventy patent-protected technologies belonging to over

⁶³ Atkinson et al., *supra* note 17, at 174; Graff et al., *supra* note 22, at 989.

⁶⁴ Atkinson et al., *supra* note 17, at 174.

⁶⁵ *Id.*

⁶⁶ Graff et al., *supra* note 22, at 992.

⁶⁷ Heller & Eisenberg, *supra* note 27, at 698.

⁶⁸ See generally Jacqueline A. Paine et al., *Improving the Nutritional Value of Golden Rice Through Increased Pro-Vitamin A Content*, 23 NATURE BIOTECHNOLOGY 482 (2005) (scientific publication that describes the preferential accumulation of beta-carotene in rice through the transgenic expression of the phytoene synthase gene from maize in combination with the *Erwinia uredovora* carotene desaturase gene).

⁶⁹ Stanley P. Kowalski & R. David Kryder, *Golden Rice: A Case Study in Intellectual Property Management and International Capacity Building*, 13 RISK 47, 51-52 (2002).

⁷⁰ *Id.* at 52.

⁷¹ *Id.* at 51-52.

⁷² Alexander J. Stein et al., *Potential Impact and Cost-Effectiveness of Golden Rice*, 24 NATURE BIOTECHNOLOGY 1200, 1201 at Table 1 (2006).

thirty public and private sector entities.⁷³ Remarkably, every owner of the IPRs required to create Golden Rice provided free licenses so that the product would be available to small farmers in developing countries.⁷⁴ It is difficult to determine whether the biotechnology companies that provided the free licenses did so as a show of humanitarianism or anticipated that such a gesture would garner larger acceptance of agricultural biotechnology.⁷⁵ No matter their motivation, those interested in creating nonprofit GM crops for purposes of food security may not necessarily find themselves in the same fortuitous situation that led to the complete and free licenses of Golden Rice.

An advantage of China's public sector-driven agricultural biotechnology industry is a lack of fragmentation among private sector entities. It is difficult to determine whether the absence of IPRs fragmentation has contributed, in parallel with a strong scientific infrastructure, to China's success in the industry. Regardless, private sector entities that refuse to license enabling technologies required for the development of GM crops currently do not hinder Chinese efforts of food security.

III. CHINA'S MEMBERSHIP IN THE WTO ENCOURAGED THE STRENGTHENING OF IPRs IN CHINA

TRIPS has applied to China since it became a member of the WTO in 2001.⁷⁶ The application of TRIPS has subsequently resulted in the strengthening and harmonization of Chinese IP laws and enforcement as mandated by the agreement.⁷⁷

A. *TRIPS Requires WTO Member States to Have Strong IPRs*

The main objective of TRIPS is to harmonize intellectual property laws, which emerged from the realization that IPRs are territorially restricted to national boundaries and have little or no protection in foreign countries that do not have similar protections.⁷⁸ With little to no protection in other countries, minimal incentive to invest or spread innovation into those

⁷³ Ronald P. Cantrell et al., *The Impact of Intellectual Property on Nonprofit Research Institutions and the Developing Countries They Serve*, 6 MINN. J. L. SCI. & TECH. 253, 269 (2004).

⁷⁴ Remigius N. Nwabueze, *What Can Genomics and Health Biotechnology Do For Developing Countries?*, 15 ALB. L.J. SCI. & TECH. 369, 394 (2005); Cantrell, *supra* note 73, at 270.

⁷⁵ Sara Boettiger & Alan Bennett, *The Bayh-Dole Act: Implications For Developing Countries*, 46 IDEA 261, 270 (2006).

⁷⁶ See TRIPS art. 1.

⁷⁷ U.S. TRADE REPRESENTATIVE, *supra* note 29, at 5.

⁷⁸ Revesz, *supra* note 32, at 5.

countries exists.⁷⁹ Although acceptance of TRIPS is mandatory for any country now interested in joining the WTO, during negotiations of the agreement in the 1990s, developing countries were politically encouraged to accept TRIPS as a WTO requirement. This occurred mainly as a result of threats of unilateral sanctions, by the United States and the European Union, against those countries that were infringing upon their IPRs.⁸⁰ Despite the ostensible lack of options presented to developing countries during the TRIPS negotiations, some benefits were provided. For example, trade restrictions were liberalized for agricultural and textile imports from developed countries to the developing countries that accepted TRIPS.⁸¹

Requiring developing countries to agree to TRIPS, and IP globalization in general, is an extremely complex and much debated topic. Opponents of IP globalization view it as an imposition of control by countries that own the majority of IPRs.⁸² However, supporters of IP globalization believe that a recipient country will benefit as a result of increased foreign investment and technology transfer,⁸³ resulting in greater economic growth.⁸⁴

The TRIPS agreement provides enforcement mechanisms in addition to compliance mechanisms in order to harmonize the member states' laws.⁸⁵ Two enforcement provisions exist under TRIPS.⁸⁶ The first relates to domestic enforcement, and requires member states to provide effective and expeditious remedies to prevent infringements.⁸⁷ The second provides for a dispute settlement mechanism between two member states through the WTO itself.⁸⁸

With respect to biotechnology, the TRIPS agreement contains important provisions necessary for the promulgation of advancements in agricultural biotechnology. Agricultural biotechnology management further poses IP-related issues. Innovations can be easily duplicated, as "seed[s] can be replanted, genes can be cloned based on sequence information, [and]

⁷⁹ E. Anthony Wayne, *Why Protecting Intellectual Property Rights Matter*, GREATWALLIP.COM, <http://www.greatwallip.com/cn/articles/why-protecting-ip-rights-matters.asp>.

⁸⁰ Revesz, *supra* note 32, at 7.

⁸¹ *Id.*

⁸² Jorge E. Mayer, *Intellectual Property Rights and Access to Agbiotech by Developing Countries*, 5 *AGBIOTECHNET* 1, 3-4 (2003).

⁸³ Keith E. Maskus, *The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer*, 9 *DUKE J. COMP. & INT'L L.* 109, 149-150 (1998).

⁸⁴ *See* Wayne, *supra* note 79.

⁸⁵ *See* TRIPS pt. III.

⁸⁶ Revesz, *supra* note 32, at 8.

⁸⁷ TRIPS art. 41; Revesz, *supra* note 32, at 8-9.

⁸⁸ TRIPS pt. V; Revesz, *supra* note 32, at 10.

methods can be copied following established protocols.”⁸⁹ This creates the demand for increased international IPRs protection for biotechnology innovations.⁹⁰ One such provision of TRIPS is the requirement that all WTO member states protect GM microorganisms.⁹¹ This provision parallels United States patent law interpreted by the landmark United States Supreme Court case in *Diamond v. Chakrabarty*, which held that bioengineered microorganisms are patentable.⁹² *Diamond* arguably provided a judicial basis upon which the biotechnology industry flourished.⁹³ Furthermore, TRIPS stipulates that plant varieties must be protected “either by patents or by an effective *sui generis* system or by any combination thereof.”⁹⁴ Still to be resolved however, is whether TRIPS should require mandatory protection of biotechnology innovations above the level of the microorganism.⁹⁵

B. *Chinese Patent Law Is Conducive To Biotechnological Innovation*

China actively engages in patenting both domestic and foreign innovations, including those essential for the progression of agricultural biotechnology. In 2005, the State Intellectual Property Office of China (“SIPO”) granted 171,000 patents to Chinese citizens, and 42,000 to foreigners.⁹⁶ Between 1985 and 1999, Chinese herbal medicines, foodstuffs, and pharmaceuticals had the largest number of patent applications.⁹⁷ China amended its patent law as recently as 2001 and remains consistent with the requirements of TRIPS.⁹⁸ One noticeable difference between U.S. and Chinese patent law is the way in which subject matter is determined. Although the United States does not specifically bar specific subject

⁸⁹ Mayer, *supra* note 82, at 2.

⁹⁰ Kevin W. McCabe, *The January 1999 Review of Article 27 of the TRIPS Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology*, 6 J. INTELL. PROP. L. 41, 50 (1998).

⁹¹ TRIPS art. 27(3)(b); Revesz, *supra* note 32, at 12; Binenbaum et al., *supra* note 17, at 311.

⁹² See generally *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (holding that bacteria genetically engineered to break down crude oil was patentable).

⁹³ Margo A. Bagley, *Academic Discourse and Proprietary Rights: Putting Patents In Their Proper Place*, 47 B.C. L. REV. 217, 234-235 (2006).

⁹⁴ TRIPS art. 27(3)(b); Binenbaum et al., *supra* note 17, at 311.

⁹⁵ Revesz, *supra* note 32, at 12.

⁹⁶ STATE INTELLECTUAL PROPERTY OFFICE OF THE PEOPLE’S REPUBLIC OF CHINA, ANNUAL REPORT, ch. XV Statistics, tbl. 3 Three Kinds of Patent[s] Granted for Home and Abroad, 1985-2005 (2005), available at http://www.sipo.gov.cn/sipo_English/ndbg/nb/ndbg2005/200605/P020060607363127165313.htm.

⁹⁷ Jacqueline Lui, *Patenting Biotechnology Inventions in China*, 19 NATURE BIOTECHNOLOGY 83, 84 (2001).

⁹⁸ *Id.* at 83.

matter,⁹⁹ a list of specifically excluded subject matter exists in Chinese patent law.¹⁰⁰

With respect to claim language, products can be either a compound, a composition, or product defined by a process.¹⁰¹ Because genetic materials are chemical structures, DNA, RNA, and chromosomes are patentable as chemical substances under Chinese patent law.¹⁰² However, such genetic materials must be isolated or purified from their natural environment and cannot be mere discoveries.¹⁰³ In addition, Chinese patent law does not allow for the patenting of plant varieties. However, methods of breeding the plant varieties are allowed.¹⁰⁴

C. *Enforcement of IPRs in China is Improving*

Although China's IP laws are consistent with the requirements of TRIPS, international concerns exist regarding the enforcement of these laws. With respect to IP protection and enforcement, China is of the highest priority for the United States.¹⁰⁵ The United States considers China to have the greatest occurrence of counterfeiting in the world.¹⁰⁶ Ninety percent of all protected goods in China are counterfeits.¹⁰⁷ To promote strong IP protection in China, the United States plans to continue to engage in bilateral discussions to encourage effective use of trade tools.¹⁰⁸ Further efforts will include the expansion of law enforcement cooperation, education and capacity building, and private sector cooperation.¹⁰⁹ Recently, the United States has been more assertive, using "high-level meetings to strongly urge China to take immediate and substantial steps to put it on the path toward compliance with its critical TRIPS Agreement obligation to make available

⁹⁹ 35 U.S.C. § 101 (2007); Lui, *supra* note 97, at 83.

¹⁰⁰ Article 25, Patent Law of the People's Republic of China (promulgated by the Standing Comm. Nat'l People's Cong., Mar. 12, 1984, amended Aug. 25, 2000, effective July 1, 2001), art. 25 (P.R.C.), http://www.sipo.gov.cn/sipo_English/flfg/zlflfg/200203/t20020327_33872.htm [hereinafter Chinese Patent Law]; Lui, *supra* note 97, at 83.

¹⁰¹ Lui, *supra* note 97, at 83.

¹⁰² *Id.*

¹⁰³ Chinese Patent Law, art. 25(1), *supra* note 100; Lui, *supra* note 97, at 83.

¹⁰⁴ Chinese Patent Law, art. 25(4), *supra* note 100; Lui, *supra* note 97, at 83.

¹⁰⁵ U.S. TRADE REPRESENTATIVE, SPECIAL 301 REPORT FOR 2005 (2006).

¹⁰⁶ U.S. TRADE REPRESENTATIVE, *supra* note 29, at 63.

¹⁰⁷ *Id.*

¹⁰⁸ THE NATIONAL INTELLECTUAL PROPERTY LAW ENFORCEMENT COUNCIL, REPORT TO THE PRESIDENT AND CONGRESS ON COORDINATION OF INTELLECTUAL PROPERTY ENFORCEMENT AND PROTECTION 31 (2006).

¹⁰⁹ *Id.*

effective enforcement mechanisms.”¹¹⁰ The United States has also been considering WTO dispute settlement options.¹¹¹

Although a significant percentage of IP violations in China are copyright and trademark issues, biotechnology continues to be a problem, as ninety seven percent of small molecule pharmaceuticals in China are copies.¹¹² Pharmaceutical (and presumably agricultural biotechnology) counterfeits are particularly worrisome with respect to safety concerns resulting from the lack of regulatory approval.¹¹³ Specific to IP violations of agricultural biotechnology innovations, the only foreign product to be commercialized in China thus far, Monsanto’s Bt cotton,¹¹⁴ has suffered economic setbacks resulting from counterfeiting.¹¹⁵

The improvement of IP enforcement is a focus of Chinese intellectual property policy. Currently, China’s IP laws and regulations provide for IP enforcement through administrative authorities, criminal prosecutions, and civil action.¹¹⁶ At the Joint Commission of Commerce and Trade meeting with the United States in 2004, China committed itself to increasing IP enforcement and agreed to move forward with legislative and judicial measures to improve its protection of IPRs.¹¹⁷ Furthermore, the National IPR[s] Protection Working Group Office formulated “China’s Action Plan on IPR[s] Protection 2006” to “better protect [] IPR[s], resolutely punish and combat various infringement and other illegal activities.”¹¹⁸ The plan focuses mainly on improving IP enforcement.¹¹⁹ With respect to patents, the plan aims to both standardize the conduct of patent agents and to revise and issue a guide on patent review.¹²⁰

China is further attempting to strengthen enforcement of its IPRs through litigation. The number of Chinese patent litigation cases has been increasing, indicating that “awareness of the exploitation and enforcement of

¹¹⁰ U.S. TRADE REPRESENTATIVE, *supra* note 29, at 59 (2004).

¹¹¹ U.S. TRADE REPRESENTATIVE, *supra* note 105.

¹¹² Hepeng Jia, *IP Litigation in China Could Drive Innovation*, 22 NATURE BIOTECHNOLOGY 368, 368 (2004).

¹¹³ U.S. TRADE REPRESENTATIVE, *supra* note 105; Wayne, *supra* note 79.

¹¹⁴ Gale et al., *supra* note 18, at 35.

¹¹⁵ LAURA J. LOPPACHER & WILLIAM A. KERR, ESTEY CENTRE FOR LAW AND ECONOMICS IN INTERNATIONAL TRADE, CHINA’S REGULATION OF BIOTECHNOLOGY—DOES IT CONFORM TO THE WTO? 28 (2004), available at http://www.esteycentre.ca/China_WTO_Biotech.pdf.

¹¹⁶ U.S. TRADE REPRESENTATIVE, *supra* note 29, at 64-67 (2004).

¹¹⁷ *Id.* at 59.

¹¹⁸ See CHINA’S ACTION PLAN ON IPR PROTECTION 2006, STATE OFFICE OF INTELLECTUAL PROPERTY PROTECTION OF THE P.R.C. (2006), http://www.ipr.gov.cn/ipr/en/info/Article.jsp?a_no=3326&col_no=102&dir=200604.

¹¹⁹ *Id.*

¹²⁰ *Id.*

intellectual property is building, and that the Chinese economy is becoming more technology-intensive.”¹²¹ Lawsuits in China related to IPRs are grouped into two types of categories: patent administrative lawsuits that are similar to criminal cases between SIPO and a private party, and patent civil lawsuits.¹²² In 2005, Chinese courts tried 3529 patent administrative lawsuits involving IPRs violations, a twenty-eight percent increase from the previous year.¹²³ Additionally, 13,393 civil cases were tried for IPRs violations in 2005, which was a thirty-eight percent increase from the previous year.¹²⁴ The increases in IPRs-related litigation appear to be part of a larger trend, as Chinese courts adjudicated a total of 23,636 IP-related cases for the entire four year period between 1998 and 2002, a forty percentage increase from the previous four year period.¹²⁵

In spite of the efforts of the United States and China, sufficient enforcement of IPRs in China continues to be a challenging undertaking. This can be attributed to a complexity of factors, including the lack of government coordination, local corruption, high thresholds for criminal prosecution, and lack of resources and training.¹²⁶ Nonetheless, China’s strengthening of its IP laws and enforcement are creating a setting more favorable to the interests of foreign agricultural biotechnology companies.

IV. STRONGER IP ENFORCEMENT IN CHINA WILL LIKELY RESULT IN IPRs FRAGMENTATION AMONG PRIVATE AND PUBLIC SECTOR ENTITIES

While the harmonization of IP laws among WTO member states has had beneficial effects, the strengthening of Chinese IP laws and enforcement is likely to have negative consequences on China’s agricultural biotechnology industry. With the increase in private sector IPRs protection, the introduction of fragmentation of IPRs among the private and public sector will occur. This will further increase the challenges China faces with respect to its efforts to ensure food security.

¹²¹ Lui, *supra* note 97, at 84.

¹²² Yalei Sun, *A Comparative Study of the Chinese Patent Law Practice Part II: Patent Litigation and Case Studies*, 7 PERSP. 5, 6 (2006).

¹²³ XIAO YANG, SUPREME PEOPLE’S COURT WORK REPORT FOR 2005 sec. 1 (2006) available at http://lawprofessors.typepad.com/china_law_prof_blog/files/spc_work_report.html.

¹²⁴ *Id.*

¹²⁵ Jia, *supra* note 112, at 368.

¹²⁶ U.S. TRADE REPRESENTATIVE, *supra* note 29, at 62-63.

A. *Foreign Agricultural Biotechnology Companies Have Historically Been Reluctant to Invest in China*

Weak IP protection may be a factor in the public sector domination of China's agricultural biotechnology. Strong IP protection in developing countries is theorized to encourage innovation while providing the economic confidence needed to attract foreign investment.¹²⁷ Foreign direct investment, which is the result of the establishment of production subsidiaries by a foreign enterprise, can be a source of capital and technology transfer.¹²⁸ Technology transfer is "the application of technologies in new geographic or product areas . . ." ¹²⁹ Subsequently, this increase in foreign investment and technology transfer will ultimately "translate into faster rates of economic growth."¹³⁰

Although maximum IP protection may not necessarily lead to the greatest amount of foreign investment,¹³¹ "various authors have found lack of enforcement to be a deterrent for foreign direct investment."¹³² This is more true with agricultural biotechnology than with other industries in China that do not have weak foreign direct investment, as the cost of developing a GM crop may be over \$150 million.¹³³ Without strong IPRs, the industry would not be able to bear the substantial investment risk associated with agricultural biotechnology.¹³⁴ As described previously, the only private sector GM crop from abroad to have been previously adopted to a substantial degree in China was a cotton variety made by Monsanto.¹³⁵ However, because of China's weak IPRs at the time, Monsanto exposed itself to "significant local piracy" of its seeds, resulting in a loss of investment income.¹³⁶

¹²⁷ Wayne, *supra* note 79; EDWIN MANSFIELD, THE WORLD BANK AND INTERNATIONAL FINANCE CORPORATION, INTELLECTUAL PROPERTY PROTECTION, FOREIGN DIRECT INVESTMENT, AND TECHNOLOGY TRANSFER, THE WORLD BANK AND INTERNATIONAL FINANCE CORPORATION 1 (1994); William Lesser, *The Effects of Intellectual Property Rights on Foreign Direct Investment and Imports into Developing Countries in the Post-TRIPS Era*, 5 IP STRATEGY TODAY 1, 2 (2002).

¹²⁸ Maskus, *supra* note 83, at 111. See also Wayne, *supra* note 79.

¹²⁹ Mayer, *supra* note 82, at 1.

¹³⁰ Wayne, *supra* note 79.

¹³¹ See Paul J. Heald, *Mowing the Playing Field: Addressing Information Distortion and Asymmetry in the TRIPS Game*, 88 MINN. L. REV. 249, 252 (2003).

¹³² Mayer, *supra* note 82, at 4.

¹³³ David L. Richer, *Intellectual Property Protection: Who Needs It?*, in AGRICULTURAL BIOTECHNOLOGY AND THE POOR 203, 204 (G.J. Persley & M.M. Lantin eds., 1999), available at <http://www.cgiar.org/biotech/rep0100/Richer.pdf>.

¹³⁴ *Id.*

¹³⁵ Gale et al., *supra* note 18, at 35.

¹³⁶ Joel I. Cohen & Robert Paarlberg, *Explaining Restricted Approval and Availability of GM Crops in Developing Countries*, 4 AGBIOTECHNET, Oct. 2002, at 1, 3.

In addition to the reluctance of foreign companies to invest in agricultural biotechnology due to investment risk, foreign agricultural biotechnology companies may be reluctant to invest in China because of protectionist measures taken by the Chinese government. One form of protectionism is based on restrictions on foreign agricultural biotechnology firms, which may be keeping many foreign agricultural biotech firms from entering the Chinese market.¹³⁷ These restrictions may have occurred “to frustrate the commercial ambitions of Western [agricultural biotechnology] firms.”¹³⁸ This apparent protectionism is possibly attributed to the desire of China’s public sector-dominated agricultural biotechnology industry to catch up to the advances made by foreign entities.¹³⁹

Protectionism in China’s biotechnology industries may eventually ease as China develops a stronger IP regime. In agricultural biotechnology’s sister industry, pharmaceuticals, recent attempts at protectionism have been unsuccessful. In 2004, the Chinese Patent Office invalidated Pfizer’s Viagra patent because of insufficient disclosure.¹⁴⁰ This decision caused immediate polarization among the Chinese and United States governments and caused the U.S. Embassy in Beijing to issue a warning that this decision may deter foreign investment due to insufficient IPRs protection.¹⁴¹ However, others commented that the decision of the Chinese Patent Office was not indicative of protectionism, but actually an indication of stronger IP protection resulting from more stringent analyses of patent applications.¹⁴² In June 2006, a Chinese court revoked the invalidation of the patent, essentially giving Pfizer patent protection for Viagra in China.¹⁴³ Whether this particular case was indicative of China’s commitment to stronger IPRs or a weakening of protectionism due to political pressures is difficult to determine. In either case, it may be viewed as yet another suggestion of confidence for the biotechnology private sector in expanding their commercial interests to China.

¹³⁷ Colin Macilwain, *Against the Grain*, 422 NATURE 111, 111 (2003).

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ Sun, *supra* note 122, at 18-20.

¹⁴¹ *Id.* at 18.

¹⁴² See Richard A. Castellano, Note, *Patent Law For New Medical Uses of Known Compounds and Pfizer’s Viagra*, 46 IDEA 283, 283-284 (2006).

¹⁴³ Lizhu Zheng, *Invalidation Decision of Viagra Patent Revoked in China*, CASRIP NEWSL., (Center for Advanced Study & Research on Intellectual Property, Seattle, WA) Spring/Summer 2006, <http://www.law.washington.edu/Casrip/Newsletter/Vol13/newsv13i2Zheng.html>.

B. *Increased Interest in Agricultural Biotechnology from Foreign Companies Would Bring with It Increased IPRs Fragmentation*

Two factors are likely to increase the presence of the private sector from abroad in China: the strengthening of IPRs and the weakening of protectionism. In 2004, Roche Pharmaceuticals announced the creation of a research and development center in China.¹⁴⁴ A major factor in convincing Roche to establish the center in China was the recent strengthening of IPRs.¹⁴⁵ It is difficult to conclusively determine whether private sector agricultural biotechnology companies from abroad will also begin to seriously invest in the Chinese market. Nonetheless, an environment conducive to private sector interests has become more favorable in recent years.

As a result of such a setting in which foreign private sector entities will no longer hesitate to invest, China will likely see an increase in foreign agricultural biotechnology companies wishing to expand the protection of their enabling technologies under Chinese law. Such technologies will unquestionably include processes that can be used to create GM crops that the public sector believes necessary to ensure food security. Consequently, emergence of the private sector will lead to issues of IPRs fragmentation among the private and public sectors as seen in other developing countries.¹⁴⁶ Accordingly, China must protect the interests of its public sector from this highly probable occurrence.

V. REQUIRING COMPULSORY LICENSING OF CRITICAL IPRs WILL FACILITATE CHINA'S OBJECTIVE OF ENSURING FOOD SECURITY

China's stronger IP laws and improvements in enforcement will likely result in IPRs fragmentation between foreign private sector agricultural biotechnology companies and China's public sector. However, the implementation of a compulsory licensing scheme could function to prevent encumbrances of advances made towards food security. Because compulsory licenses would be granted for selected enabling technologies used to create GM crops, and not the product itself, such licensing would not raise substantial concerns of parallel importing. As a result, concerns of compromised innovation would be minimal.

¹⁴⁴ Jia, *supra* note 112, at 368.

¹⁴⁵ *Id.*

¹⁴⁶ See Atkinson et al., *supra* note 17, at 174.

A. *TRIPS and Chinese Patent Law Permit Compulsory Licensing*

Compulsory licenses can be utilized to force an IPRs owner to share its protected technology. A compulsory license is a type of nonexclusive license resulting from governmental action.¹⁴⁷ It allows one party to produce a protected product or process without the consent of another party that owns the rights to the intellectual property.¹⁴⁸ The policy behind compulsory licensing is to adjust “the balance between public interests and the private interests of patent holders by providing an exception to the exclusive rights normally provided by [an intellectual property right].”¹⁴⁹

While TRIPS doesn’t explicitly use the phrase “compulsory licensing,” the phrase “other use without authorization of the right holder” found in Article 31 implies that it permits WTO member states to include a compulsory licensing provision in their IP laws.¹⁵⁰ However, compulsory licensing “can only be done under a number of conditions aimed at protecting the legitimate interests of the patent holder.”¹⁵¹ The constraints must meet at least one of five “broadly defined public purposes: (1) to ameliorate a refusal to deal (essentially a failure to work the patent); (2) to address a health or other emergency of extreme urgency; (3) to resolve anticompetitive practices; (4) for noncommercial use; and (5) for dependent patents.”¹⁵²

Chinese patent law permits compulsory licensing under requisite conditions.¹⁵³ However, a compulsory license has never been granted against a non-Chinese corporation’s protected property.¹⁵⁴ Apart from this fact, China is not prohibited from licensing a foreign corporation’s technology that is protected under Chinese patent law, as long as Article 31 of TRIPS is not violated.

¹⁴⁷ World Trade Organization, *Fact Sheet: Trips and Pharmaceutical Patents, Obligations and exceptions*, http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#compulsorylicensing (last visited Jan. 28, 2007).

¹⁴⁸ *Id.*

¹⁴⁹ Michael R. Taylor & Jerry Cayford, *American Patent Policy, Biotechnology, and African Agriculture: The Case for Policy Change*, 17 HARV. J. L. & TECH. 321, 361 (2004).

¹⁵⁰ TRIPS art. 31; World Trade Organization, *supra* note 147.

¹⁵¹ World Trade Organization, *supra* note 147.

¹⁵² MICHAEL R. TAYLOR & JERRY CAYFORD, RESOURCES FOR THE FUTURE, THE U.S. PATENT SYSTEM AND DEVELOPING COUNTRY ACCESS TO BIOTECHNOLOGY: DOES THE BALANCE NEED ADJUSTING? 61-62 (2002), available at <http://www.rff.org/rff/Documents/RFF-DP-02-51.pdf>; see also TRIPS art. 31.

¹⁵³ Chinese Patent Law, *supra* note 100, ch. VI.

¹⁵⁴ Lily Lim, *Trends in Compulsory Licenses in Greater China*, IP LAW360, Aug. 16, 2006, <http://ip.law360.com/secure/ViewArticle.aspx?Id=8753>.

B. *Compulsory Licensing Is Controversial Due to Concerns that Such Licenses May Deter Innovation*

Proponents of compulsory licensing claim that public interest matters of public health and welfare outweigh the exclusive rights of an IPRs owner.¹⁵⁵ The idea of using compulsory licenses is most common with respect to providing readily available drugs in the developed world to developing countries; most notably for HIV drugs in Africa.¹⁵⁶ However, proposals that suggest the use of compulsory licensing for technologies related to food security have been comparatively minimal.¹⁵⁷

Compulsory licensing is not free from criticism. Because strong IPRs are necessary to drive innovation, an argument against compulsory licensing is that investment in potential inventions would be “less secure and less attractive” to the innovator.¹⁵⁸ As director of the National Institutes of Health, Harold Varmus stated with respect to nonexclusive licenses in general, “[i]t is well documented that technologies with potential as therapeutics are rarely developed into products without some form of exclusivity, given the large development costs associated with bringing the product to the market.”¹⁵⁹ Thus, at least with respect to the pharmaceutical industry, compulsory licenses should only be granted under exceptional circumstances.

The loss of incentive to innovate specifically associated with compulsory licensing occurs mainly because such licenses encourage parallel importing.¹⁶⁰ Parallel importing, otherwise known as the gray market, takes place when a product that is provided inexpensively to one country is sold to another country where a lucrative market exists, but without permission from the IPRs holder.¹⁶¹ With respect to

¹⁵⁵ Kirby W. Lee, Note, *Permitted Use of Patented Inventions in the United States: Why Prescription Drugs Do Not Merit Compulsory Licensing*, 36 IND. L. REV. 175, 181 (2003).

¹⁵⁶ See generally Alberto do Amaral Junior, *Compulsory Licensing and Access to Medicine in Developing Countries*, SELA 2005 PANEL 5: POVERTY AND THE INTERNATIONAL ORDER (2005), available at [http://islandia.law.yale.edu/sela/SELA%202005/Alberto%20Amaral%20\(Final%20English%20Version\)%20v%201.0.pdf](http://islandia.law.yale.edu/sela/SELA%202005/Alberto%20Amaral%20(Final%20English%20Version)%20v%201.0.pdf).

¹⁵⁷ See Robert H. Trudell, *supra* note 6, at 310; Taylor & Cayford, *supra* note 149, at 368; see *infra* Part V.C.

¹⁵⁸ Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and the Reality*, 33 IDEA 349, 357-358 (1993).

¹⁵⁹ Don Allen Resnikoff, *Federally Funded Stem Cell Research: A Good Deal For the Taxpayer and Consumer?*, 14 LOY. CONSUMER L. REV. 36, 50 (2001) (quoting a letter from Harold Varmus, Director, National Institutes of Health, to Ralph Nader, James Love, and Robert Weissman (Oct. 19, 1999), available at <http://www.cptech.org/ip/health/sa/varmusletteroct19.html>).

¹⁶⁰ Dana Ziker, *Facilitating Access of AIDS Drugs While Maintaining Strong Patent Protection*, 2001 DUKE L. & TECH. REV. 42, 17 (2001).

¹⁶¹ *Id.*

pharmaceuticals, it is argued that compulsory licensing schemes will actually decrease the access to life-saving drugs by reducing the innovative incentive to research and develop the original drug.¹⁶² This would result because the generic drug manufacturers would never have the opportunity to copy the original compound.¹⁶³

Various royalty arrangements have been proposed to deal with the issue of lost incentive resulting from forced licenses.¹⁶⁴ Such schemes could create incentive by either providing an upfront fee to the IPRs holder that was forced to give up his or her rights, or provide payments as the commercial value is determined.¹⁶⁵ Thus, it has been argued that reasonable royalties resulting from compulsory licensing would not significantly discourage the investment required to innovate.¹⁶⁶ However, whether a royalty scheme is even appropriate for a compulsory license provided to a public sector entity for technologies leading to a product with low commercial value is questionable.¹⁶⁷

C. *China Should Take Advantage of the Flexibility of TRIPS to Utilize Compulsory Licenses for Technologies Critical to Food Security*

China should utilize the emergency language¹⁶⁸ of the compulsory licensing provisions of TRIPS to allow compulsory licensing of technologies critical for food security.¹⁶⁹ In response to concerns that TRIPS might hinder efforts to control diseases of public health importance such as HIV, tuberculosis, and malaria, WTO members adopted a special Ministerial Declaration on November 14, 2001 at the WTO Ministerial Conference in Doha.¹⁷⁰ The conference resulted in the further adoption of the Doha

¹⁶² See Lee, *supra* note 155, at 195; Joseph A. Yosick, Note, *Compulsory Patent Licensing For Efficient Use of Inventions*, 2001 U. ILL. L. REV. 1275, 1301 (2001).

¹⁶³ Lee, *supra* note 155, at 195-96; Yosick, *supra* note 162, at 1301 (arguing that compulsory licenses would have a "detrimental effect on the development of new medicines," hence precluding the existence of original drugs that are available for generic drug makers to copy).

¹⁶⁴ Ruth E. Freeburg, Comment, *No Safe Harbor and No Experimental Use: Is It Time for Compulsory Licensing of Biotech Tools?*, 53 BUFF. L. REV. 351, 412-413 (2005).

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*; see also Yosick, *supra* note 162, at 1292.

¹⁶⁷ See discussion *infra* Part V.C, pertaining to the innovative effects of proposing compulsory licenses for technologies related to food security in China.

¹⁶⁸ See TRIPS, art. 31.

¹⁶⁹ See discussion *infra* Part V.D, about concerns that the compulsory licenses suggested in this section would threaten innovation.

¹⁷⁰ World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration]; World Health Organization, *The Doha Declaration on the TRIPS Agreement and Public Health*, http://www.who.int/medicines/areas/policy/doha_declaration/en/index.html (last visited Apr. 12, 2007).

Declaration on the TRIPS Agreement and Public Health (“Doha Declaration on TRIPS”),¹⁷¹ which reaffirmed flexibility for TRIPS member states in circumventing IPRs for sufficient access to essential medicine.¹⁷² This Declaration not only reaffirms the right to grant compulsory licenses and to determine the grounds upon which such licenses are granted, but allows each member state to determine what constitutes a “national emergency or other circumstance[] of extreme urgency”¹⁷³

In 2003, the WTO implemented a provision that permits WTO member states to make drugs for an overseas market if they receive notice from a country with inadequate manufacturing capacity of its own.¹⁷⁴ As a result, China’s IP implemented the 2003 WTO decision through Order 37, an administrative order further interpreting Chinese Patent Law.¹⁷⁵ China’s Order 37 substantiates the willingness of China to implement WTO declaratory provisions pertaining to compulsory licensing.

TRIPS does not prohibit the use of compulsory licenses for technologies relevant to food security. This is exemplified by the fact that the Doha Declaration on TRIPS did not clarify the term “national emergency” as it relates to when such licenses may be granted.¹⁷⁶ As a result, this flexibility in interpreting TRIPS will actually benefit China’s public sector. China could, therefore, declare food shortages a national emergency, which would subsequently authorize the use of compulsory licenses for technologies required to create relevant GM crops. For these reasons, China should issue an administrative order similar to Order 37 that would implement the Doha Declaration on TRIPS and interpret significant hunger or malnutrition as a national emergency to reserve the right to grant compulsory licenses for such purposes.

Proposals to grant compulsory licenses to address issues of food security have only considered whether such licenses would be feasible if granted by the United States.¹⁷⁷ More specifically, these arguments

¹⁷¹ World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of 14 Nov. 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002).

¹⁷² *Id.*

¹⁷³ *Id.* at ¶ 5.

¹⁷⁴ Emma Barraclough, *China to Export Drugs Under Compulsory Licenses*, MANAGING INTELL. PROP., Dec. 12, 2005, <http://www.managingip.com/default.asp?Page=9&PUBid=198&ISS=21054&SID=603061> (last visited Apr. 12, 2007).

¹⁷⁵ *Id.*; Order 37, Measures to Implement Public Health-Related Compulsory Licensing, (promulgated by the State Intellectual Property Office, Nov. 29, 2005), translated at http://www.sipo.gov.cn/dfzz/jilin/zcfg/gjzscql/200604/t20060425_97248.htm (last visited Apr. 12, 2007).

¹⁷⁶ Katharine W. Sands, Comment, *Prescription Drugs: India Values Their Compulsory Licensing Provision—Should the United States Follow in India’s Footsteps?*, 29 HOUS. J. INT’L L. 191, 197 (2006).

¹⁷⁷ Robert H. Trudell, *supra* note 6, at 310-311; Taylor & Cayford, *supra* note 149, at 368.

discussed the ways in which the United States has failed to address how “the compulsory license provisions in Article 31 [of TRIPS] would apply to allow access to the tools of biotechnology for developing-country food security purposes.”¹⁷⁸ This comment proposes, in broad terms, that developing countries that are WTO member states should utilize their ability to grant compulsory licenses if necessary to ensure food security. In narrower terms, this comment argues that compulsory licenses for issues of food security would be most advantageous to China as a result of its already successful agricultural biotechnology industry. Accordingly, China could use these measures to protect its interests in ensuring food security without violating its WTO obligations under TRIPS.

D. China Should Not Refrain from Granting Compulsory Licenses Due to Concerns that Doing So Might Interfere with Innovation

Compulsory licensing of IPRs for technologies critical to food security in China will not deter innovation. The scenario in which compulsory licenses would be utilized in China will result after the introduction of a commercialized GM crop into the Chinese market by a foreign agricultural biotechnology company. The foreign company will likely anticipate being granted some sort of IP protection under Chinese law for the essential enabling technologies used to create the GM crop.

The demand for a compulsory license may occur in one of two ways if the Chinese public sector develops its own GM crop essential for food security. First, the Chinese entity could autonomously develop a similar technology that falls within the scope of the protection provided to the private sector entity. Conversely, the Chinese entity might simply recognize the technology as being necessary to develop a particularly vital GM crop and wish to adapt it to its own research and development. In either scenario, a compulsory license may be granted to create the GM crop necessary for food security if China were to interpret significant hunger or malnutrition as a national emergency as permitted by the Doha Declaration on TRIPS.¹⁷⁹

Incentive to innovate on the side of the private sector company will not be compromised if the Chinese government grants compulsory licenses in the requisite scenario. This results from the fact that the license will only be enforceable in China and will be used solely by China’s public sector for noncommercial purposes. More importantly, issues of parallel importing with respect to GM crops will not be as significant as with pharmaceuticals.

¹⁷⁸ Taylor & Cayford, *supra* note 149, at 368.

¹⁷⁹ See *supra* Part V.B.

With pharmaceuticals, concerns of compromised innovation occur when a patented product, the drug itself, experiences parallel importing. In contrast, because the compulsory licenses that this comment suggests would only be granted by the Chinese government for selected enabling technologies, and not for the GM crop as a whole, parallel importing would be less of a concern.

Even if parallel importation of GM crops does occur, most of the GM crops currently created by China's public sector do not have significant commercial value. As a result, the same technologies could still be used to create additional GM crops with high commercial value in the same country where the GM crops might be parallel imported to. This would allow the IPRs owner to retain his or her investment interest. This comment, therefore, suggests that with respect to agricultural biotechnology, concerns of lost innovation resulting from a gray market should be decoupled from similar concerns that are omnipresent within the pharmaceutical industry. Hence, granting compulsory licenses for noncommercial crops that will be utilized only in China would not be grounds for foreign companies to lose their incentive to innovate these technologies for additional markets that are more favorable to financial recovery.

Notwithstanding the fact this comment argues that a compulsory licensing scheme geared towards ensuring food security will not compromise innovation, China should nonetheless be sensitive to how the private sector might perceive such licenses. This results from the likelihood that the introduction of foreign technology could actually benefit China's future efforts of ensuring food security, in spite of IPRs fragmentation. One must only look at the promise of Golden Rice,¹⁸⁰ despite the fact that the creation of most GM crops will not experience similar cooperation among the private sector.¹⁸¹ As a result, China should not hesitate to exercise its ability to grant compulsory licenses for fear that doing so might discourage any humanitarian effort provided for by the private sector, no matter how unlikely such effort might seem.

VI. CONCLUSION

GM crops have the potential to alleviate chronic malnutrition and hunger, to make more efficient use of farmland, and to further reduce soil

¹⁸⁰ Stein et al., *supra* note 72, at 1201.

¹⁸¹ See Boettiger & Bennett, *supra* note 75, at 270.

erosion and the use of pesticides.¹⁸² Agricultural biotechnology is not a panacea that will solve world hunger,¹⁸³ but it is one promising way in which the problem can be addressed.¹⁸⁴ As a result of continued population growth, global warming, and other environmental factors that are contributing to the challenges of food security,¹⁸⁵ it may be argued that it is unethical not to recognize agricultural biotechnology's potential with respect to the world's hungry.

China is likely to see an increase in the presence of agricultural biotechnology companies from abroad, possibly utilizing China's stronger IP laws and enforcement as a way to protect their investments. Because of the significant financial investment required to create a GM crop, agricultural biotechnology companies have been more hesitant to invest in China than have other industries. In addition to strong IP protection, other factors such as protectionism and the difficulties associated with GM crop management,¹⁸⁶ may determine whether the private sector will attempt to import their technologies into China. All the same, the probability that the private sector will begin to seek protection under Chinese law of their enabling technologies used to create GM crops in the near future is becoming more likely.

China must, therefore, prepare for the consequences that will arise as a result of the strengthening of its IP laws. Because the broad language of TRIPS does not prohibit the declaration of a food shortage as a national emergency, China should not hesitate to grant compulsory licenses against foreign agricultural biotechnology companies. Such licenses would not raise considerable concerns of parallel importing and, therefore, the incentive to innovate would not be defeated. The result would provide for protection against the limitations on the availability of technologies critical for food security that may result from the recent strengthening of China's IP laws and enforcement.

¹⁸² BIO.ORG, *Benefits of Agricultural Biotechnology*, BIO.ORG, <http://www.bio.org/foodag/action/fact2.asp> (last visited Apr. 12, 2007).

¹⁸³ Mitra et al., *supra* note 7.

¹⁸⁴ *Id.*

¹⁸⁵ See Udombana, *supra* note 39, at 317; Sacks & Rosenzweig, *supra* note 39; Vasil, *supra* note 39, at 399; ASIAN DEVELOPMENT BANK, *supra* note 39, at 4.

¹⁸⁶ See generally Mayer, *supra* note 82, at 2 (discussing the difficulty of enforcing the IPRs associated with GM crops).