A DYNASTY WEANED FROM BIOTECHNOLOGY: THE EMERGING FACE OF CHINA

INTRODUCTION

Although China has been slow to revolutionize its intellectual property laws by Western standards, the recent amendments made to this body of law combined with their expanding legal system have nonetheless allowed China to successfully participate in the multi-billion dollar industry of biomedicine. Through the use of joint ventures, the Chinese have lured approximately 1,500 foreign companies into the area of biomedical technology.[1] These companies will produce new biopharmaceuticals with an estimated market value of billions worldwide. Since China has invested in biotechnology for the last eight to ten years and has simultaneously renovated its intellectual property laws, the country has brilliantly enabled itself to wholly embrace an extremely profitable industry. This note will explore the likelihood of China's success in biotechnology and examine the potential difficulties that it may face.

I. BIOTECHNOLOGY DEFINED

Biotechnology is the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services.[2] More simply stated, biotechnology is the engineering and technology of the interaction between man and machines.[3] In the field of biomedicine, the biotechnology industry uses the genetically based characteristics in microorganisms and animals to create drugs and drug therapies.[4] These drugs may prevent, cure or in some way alleviate diseases. Biomedical research has produced drugs to treat cancer, hepatitis B, asthma, AIDS and numerous other afflictions.[5] As a result of these medical breakthroughs, there has been an increased need for culture and plant stock collections which can provide the basic source material for later genetic modification of existing organisms. The result of a genetic modification may be the discovery of a new cure or treatment for a disease.

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1. *Chinese/European Collaboration*, BIOTECHNOLOGY BUS. NEWS, June 3, 1994, at 14.
2. ALAN T. BULL ET. AL., BIOTECHNOLOGY: INTERNATIONAL TRENDS AND PERSPECTIVES 21 (1982).
3. AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 190 (3d ed. 1992).
4. Akim F. Czmus, *Biotechnology Protection in Japan, the European Community, and the United States*, 8 TEMP. INT'L & COMP. L.J. 435 (1994).
5. *Id.* at 436.

Biotechnology has also been utilized to treat growing environmental and agricultural concerns. Several companies, for example, have used biotechnology to produce an insecticidal protein that is effective against certain harmful insect species.[6] In addition, many companies are genetically engineering animals and plants to either produce a high yield or to increase quality.[7] Due to the substantial benefits already incurred from this area, the world has come to rely on biotechnological research for advances in medicine, pharmacology, and food production.

II. The Development of Intellectual Property Protection for Biotechnology in China

In both China and the West, intellectual property law began not as effort to provide incentives to creators by establishing a system of compensation and protection for their work, but rather as an incentive not to publish heterodox materials.[8] In England, for example, the Crown limited the unauthorized copying of books due to their desire to provide printers with an incentive not to publish materials against the state interest.[9] Similarly, in Imperial China, restrictions on the unauthorized reproduction of certain books were for the maintenance of imperial legitimacy and power.[10] The seventeenth and eighteenth centuries in the West, however, brought the development of intellectual property law as we now know it; the supplying of authors and inventors with a property interest in their creations.[11] China, on the other hand, under Confucian ideology, established a disdain for commercial profit based on the belief that true scholars wrote for edification and moral renewal. In fact, there was a general attitude of tolerance, or indeed willingness, on the part of the great Chinese painters towards the forging of their own works for it demonstrated the quality of the work and the creator's degree of civility and understanding.[12] Thus, China's laws concerning intellectual property developed far differently from those of the Western states, appearing not to resemble Western laws again until centuries later in the early 1980's.

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6. *Ecogen Signs Chinese Collaboration*, Biotechnology Bus. News, June 4, 1993, at 17.

7. Czmus, *supra* note 4, at 436.

8. William P. Alford, Comment, *Don't Stop Thinking About Yesterday: Why There Was No Indigenous Counterparts to Intellectual Property Law in Imperial China,* 7 J. Chinese L. 3, 4 (1993)

9. *Id.* at 9.

10. *Id.* at 3.

11. *Id.* at 9.

12. Alford, *supra* note 8, at 17.

Accordingly, it was not until 1985 that China adopted its first patent law to facilitate trade and establish a legal framework for foreign exchange.[13] The law provided for the granting of patents in three areas: (1) inventions for a 15 year term; (2) utility models; and (3) designs for a 5 year term, renewable for an additional 3 years.[14] The 1985 Patent Law was intended to reassure foreigners involved in technology license agreements that industrial designs not yet publicly disclosed would have legal protection, and to promote the development of science and technology for the needs of modernization.[15] The drawback of the 1985 Patent Law was that it provided little protection to pharmaceutical and chemical companies and it did not recognize services.[16]

Then, in 1991, China revised the 1985 Patent Law. Although the amendments were somewhat helpful, foreign states felt that there was not adequate protection for their works in China. Therefore, on January 17, 1992, the United States and China signed a Memorandum of Understanding (hereinafter "MOU") to solve these problems. In compliance with MOU, China made another set of amendments to its patent law in 1993. Among the most substantial changes were the extension of the duration of patent protection and the enlargement of patent protection to new pharmaceutical and chemical inventions.[17] Although China did not permit the patenting of plant and animal varieties, it did permit patents on microbiological processes and their products.[18] This new law should encourage investment in biotechnology research and development in China and is expected to cause an increase in the importation of chemical and pharmaceutical products.[19] Thus, by drastically changing its intellectual property laws in a period of only eight years, China is clearly seeking to stimulate scientific and technical personnel to produce creations and to attract foreign firms.

A. Two Means of Patent Law Enforcement in China

The government of China has expended significant efforts to accommodate the increasing volume of patent litigation by creating a special intellectual property division of the People's Intermediate Court in

13. Hamideh Ramjerdi & Anthony D'Amato, *The Intellectual Property Rights Laws of the People's Republic of China*, 21 N.C. J.INT'L. & COM. REG. 169, 175 (1995).
14. *Id.* at 176.
15. *Id.* at 176.
16. *Id.* at 176.
17. *Id.* at 177.
18. Davis Hill &Judith Evans, Comment, *Chinese Patent Law: Recent Changes Align China More Closely With Modern International Practice*, 27 GEO. WASH. J. INT'L & ECON. 359, 364 (1993-1994).
19. *Id.* at 361.

Beijing.[20] Instead of soliciting judges from China's old cadre system, the government sought to staff the intellectual property courts with a new contingent of judges.[21] China has followed an identical procedure in the courts of several provinces, municipalities and economic zones.[22] The increased volume of lawsuits demonstrates a growing confidence in the ability of China to enforce its intellectual property laws. Since the culture has a predominant aversion to litigation,[23] China has also offered other means of dispute resolution. Plaintiffs may seek conciliation, mediation, arbitration or settlement through the Administrative Authorities for Patent Affairs.[24] Through this system, adversaries in a patent dispute may rely on government officials to resolve their disagreements.[25] The Authorities have a strong local presence and connections to other local agencies which help them to make settlements without proceeding to the courts. In addition, the Administrative Authorities have concurrent jurisdiction with the People's Courts over patent infringement actions and have the power to order monetary compensation or an injunction against the infringer.[26]

While this picture of China's ability to enforce its intellectual property laws appears very bright, it is important to remember that the entire concept of patentable intellectual property is relatively new to China. Many Chinese citizens and businesses are not aware of their right to protect intellectual property.[27] In addition, the judges who preside over intellectual property disputes are typically inexperienced law school graduates because no older class qualified to hear such a dispute exists.[28] Moreover, investigations and dispute settlements are costly, time-consuming and complicated, and there is a shortage of Chinese lawyers trained in intellectual property law.[29] China is also riddled with corruption, causing regulations to be interpreted inconsistently from one government agency or ministry to the next.[30] As evidence of this widespread corruption, the United States Trade Representative reported that the estimated losses due to Chinese intellectual property infringe-

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20. *Id.* at 372.
21. *Id.* at 372.
22. *Id.* at 372.
23. *Id.* at 373.
24. *Id.* at 373.
25. *Id.* at 364.
26. *Id.* at 364.
27. Meredith A. Harper, *International Protection of Intellectual Property Rights in the 1990's: Will Trade Barriers and Pirating Practices in the Audiovisual Industry Continue*, 25 CAL. W. INT'L L. J. 153 (1994).
28. *Id.*
29. *Id.*
30. *Id.*

ments in 1993 alone were $50 million.[31] Thus, the legal system that appears effective on paper is often futile in reality, spreading alarm to foreign investors who are seeking intellectual property protection over their technology transfers. As a result, China initiated a nationwide campaign to publicize the system of intellectual property protection and to educate and train professionals in this field.[32] Therefore, while China is to be applauded for the enormous quantity of positive changes that it has made in intellectual property law in an extremely short period of time, it is unrealistic to expect China's new system to function smoothly at the outset.

III. The Status of International Intellectual Property Protection for Biotechnology and China's Role in the International Arena

In general, there are two prevalent views evident in the international conventions that address the subject of biotechnology. Private industry in developed countries, who typically produce superior biotech products, prefer the most expansive set of rights to protect their new technologies.[33] Developing countries, on the other hand, want private[34]industry in developed countries to surrender certain rights in consideration for the benefits to be realized under a universal patent system.[35] Furthermore, developing countries would like to receive the transfer of new biotechnologies without having to compensate the developed states.[36] Without the ability to receive free technology transfers, most developing countries could not afford to pay for the rights to costly biotech products. In addition, developing countries would also like to exclude living organisms from the scope of protectable subject matter for a significant percentage of genetic material used in bioengineering new plants and animals is native to their countries.[37]

The World Intellectual Property Organization (hereinafter WIPO) was created on July 14, 1967 as a specialized agency to the United Nations.[38] WIPO was constructed as an administrative body to oversee the

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31. *Id.* at 165

32. Hill and Evans, *supra* note 18, at 371.

33. David G. Scalise & Daniel Nugent, Comment, *International Intellectual Property Protections for Living Matter: Biotechnology, Multinational Conventions and the Exception for Agriculture*, 27 Case W. Res. J. Int'l L. 83, 105 (1995).

34. *Id.* at 105.

35. *Id.* at 107.

36. *Id.* at 111.

37. *Id.* at 107.

38. Convention Establishing the World Intellectual Property Organization, July 7, 1967, 828 U.N.T.S. 3.

Paris Union on the Protection of Industrial Property and to provide a forum to harmonize future intellectual property laws. Since 1967, WIPO has convened four diplomatic conferences to revise the law. WIPO primarily caters to developing states by including provisions that would require technology transfers to developing countries, authorize compulsory licensing of protected technology and other substantial limitations on the rights of patent holders. In the same vein, WIPO refuses to include new plant varieties within the scope of patent protection, which blocks adequate intellectual property protection in biotechnological advancements.[39] WIPO also excuses the obligation to compensate the inventor, which denies biotechnology companies the ability to receive a return for their investments in the research and development of new technologies.[40] As a result, the developed states of North America, Europe and Asia do not endorse WIPO's efforts.[41]

China, on the other hand, joined WIPO in 1983 to demonstrate its intention to meet international standards of intellectual property protection.[42] Furthermore, China's ratification of WIPO occurred at approximately the same time as the emergence of its new patent laws. These two dramatic developments, coupled with China's recent biotechnology activity, clearly support the idea that China has strategically planned for the emergence of a highly significant biotechnology industry.

A second multilateral treaty that concerns biotechnology is the Convention on Biological Diversity.[43] Formed in 1992, the Convention aimed to conserve biological diversity, maintain the sustainable use of biological components, and to promote the fair and equitable sharing of benefits arising out of genetic resources.[44] Despite the United States' refusal to adopt the treaty at that time, 162 other countries have agreed to its terms. While the Clinton Administration supported most of the treaty's goals, the U.S. nevertheless could not accept the idea of the "equitable share," which would force inventors to transfer their technologies to developing countries without compensation. The treaty also suggested that any income earned from the sales of technology be shared with the country that contributes the biological material.[45] The concept of shared income was borne out of an international concern that bi-

39. Scalise and Nugent, *supra* note 31, 107.

40. *Id.* at 107.

41. *Id.* at 107.

42. Laurence P. Harrington, Note, *Recent Amendments to China's Patent Law: The Emperor's New Clothes*, 17 B. C. INT'L & COMP. L. REV. 337 (1994).

43. Convention on Biological Diversity, June 5, 1992, S. TREATY DOC. No. 20, 31 I.L.M. 818 (1993).

44. *Id.*

45. Scalise and Nugent, *supra* note 31, at 110.

otechnological and pharmaceutical corporations of developed states were using indigenous flora and fauna from developing countries to manufacture their discoveries.[46] The founders of the treaty had observed foreign companies exploit and profit from the resources of developing countries, who lacked the economic strength to buy the new technologies made from their own raw materials.[47]

On June 4, 1993, the Clinton Administration signed the treaty, but later submitted a letter of interpretation securing the U.S. position on technology transfers.[48] The letter announced that transfers of proprietary technology would occur only at the discretion of, and with the voluntary consent of the owner of the technology.[49] While the international community greatly resented the United States' unilateral renegotiation of the treaty, it is important to note that if the biotechnology industry perceives low economic returns on an investment due to an international convention, then little money will be invested in that area, thereby decreasing the possibility for the creation of new drugs or vaccines.

China signed the Convention on Biological Diversity on June 11, 1992.[50] While China would undoubtedly like to see the biotechnology industry expand, it also has a need to protect itself from foreign exploitation. Many of the new biopharmaceuticals are derived from plant and animal life native to the Chinese highlands.[51] Therefore, if China fails to procure protection from global treaties, foreign companies may completely exploit Chinese flora and fauna without supplying compensation to the Chinese. Besides relying on treaties for protection, China has initiated numerous joint ventures to circumvent the dilemma of attracting foreign research and investment in biomedicine without losing all of its rights to the final product.

The General Agreement on Tariffs and Trade (hereinafter GATT) was established in 1947. GATT has a division devoted exclusively to intellectual property issues, aptly entitled the agreement on Trade Related Intellectual Property Rights (hereinafter TRIPS).[52] TRIPS seeks to assist the developed countries in receiving adequate intellectual property protection for biotechnology. Since the United States loses an estimated $60 billion annually from patent violations by developing countries, it

46. *Id.* at 110.
47. *Id.* at 111.
48. *Id.* at 112.
49. *Id.* at 112.
50. Convention on Biological Diversity, *supra* note 43, at 1004.
51. *Biotechnology Profile: A New Industry Mushrooms*, HONG KONG INDUSTRIALIST, May 1, 1997.
52. General Agreement on Tariffs and Trade, Oct, 30, 1947, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194.

has become an avid supporter of TRIPS.[53] As a result of the U.S. endorsement, TRIPS has been widely embraced by developed states like Japan and the European Community, who have joined the United States in their desire for a universally accepted system of intellectual property protections.[54] In 1990, TRIPS proposed to authorize patents for living organisms and biological processes which would also encompass microorganisms, seeds, plants and animals.[55] The developing states, however, have opposed GATT's attempt to cover patent issues, and would rather see these disputes settled in WIPO.

In addition, the developing countries have made their support of TRIPS contingent upon the removal of microorganisms and microbiological processes for the production of plants and animals as patentable subject matter. These countries want to narrow the patentable area of biotechnology so that only living organisms and biological processes that are achieved by traditional breeding methods are protected.[56] Consequently, the developing states want biopharmaceuticals excluded from intellectual property protection, which is the area of biotech that has the greatest potential for commercial gain.

In the spring of 1996, the World Health Organization (hereinafter 'WHO') called for the clarification of whether or not TRIPS protected the patent rights of biotechnology processes and products.[57] While TRIPS has made the patenting of pharmaceuticals compulsory, the agreement does not specify whether biotech processes should be patented, such as the replication of a naturally existing gene for a human protein.[58] As a result, TRIPS may undergo changes in the next four years. In the meantime, WHO will be pressing for amendments to have TRIPS clarify its position on biotechnology.[59]

The development of China's patent law has enabled it to conform with the GATT agreement on TRIPS.[60] Since China is currently in the process of cultivating and expanding its biotechnology industry, China has not ascribed to the views of the other developing countries, who are against intellectual property protection for biopharmaceuticals. Rather,

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53. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr.15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31; 33 I.L.M. 81 (1994).

54. Scalise and Nugent, *supra* note 31, at 114.

55. *Id.* at 114.

56. *Id.* at 115.

57. *WHO Wants Patent Confusion Cleared Up*, BIOTECHNOLOGY BUS. NEWS, Apr. 10, 1996, at 2.

58. *Id.*

59. *Id.*

60. Hill and Evans, *supra* note 18, at 359.

China has sought to prove that it is ready to comply with modern international practice in the enforcement of intellectual property protection.[61] In addition, China would not support the views of the developing countries, for such support would essentially block both the establishment of their biopharmaceutical industry and the profits that could be derived therein.

China has also become a member of the Patent Cooperation Treaty (hereinafter PCT) which was unanimously approved at the plenary session of the 20th General Assembly of the PCT in September 1992.[62] Since complying with the PCT, China is performing international patent searches and preliminary examinations.[63] China's participation in this treaty and its willingness to enter into international searches is yet another example of China's drive to compete in the global market of biotechnology.

Furthermore, China has shown support for the International Centre for Genetic Engineering and Biotechnology (hereinafter ICGEB) based in Geneva. The ICGEB was also established by the United Nations Industrial Development Organization in 1987 to create biotech discoveries in developing countries.[64] The ICGEB has recently signed a number of licensing agreements with industries in its member states to transfer technology that could lead to new products being manufactured by developing countries.[65]

As a result of China's participation in these international agreements regarding the intellectual property protection of biotechnology, China has begun to demonstrate to the international community that it has not only been willing to revamp its laws in favor of modern practice, but has also been willing to become an international figure in the industry. The massive reconstruction of Chinese law and the Chinese accession to global treaties should not be lightly discounted when one considers that China's former isolationist policies had dominated its foreign relations law for centuries. Thus, the dramatic shift in Chinese foreign policy and intellectual property law should secure China a successful position in the field of biotechnology, provided that China can continue to evolve its internal political system.

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61. *Id.* at 359.

62. Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 230.

63. Hill and Evans, *supra* note 18, at 359.

64. *New Push for Biotech Products in Developing Countries*, BIOTECHNOLOGY BUS. NEWS, Mar. 12, 1996, at 3.

65. *Id.*

IV. The Emergence of China's Biotechnology Industry

China has devoted a decade of governmental investment in its biomed/biotech industry with the hopes of attaining substantial capital dividends in its commercial applications. This year China announced plans to raise its biomedical industry level to that of Western standards by 2004.[66] In order to achieve this end, the Chinese Pharmaceutical Administration determined that it would focus future research on genetic and protein engineering.[67] Although many of China's domestically produced biomedical products are adaptations of existing foreign developed technology, China has recently created government programs designed to help research institutions commercialize their work.[68] Coupled with the funding for these research institutions, China has also striven to update its intellectual property protection in order to provide an environment suitable for the biomed/biotech industry. Over the last few years, China has attracted nearly 1,500 foreign funded biopharmaceutical enterprises amounting in a $4.1 billion capital investment.[69] Furthermore, seven national level research and development centers and laboratories have been established in Shanghai and six national engineering research centers are currently under construction there.[70] As a result of these new research and development centers, Shanghai has been labeled the most important "pharmaceutical valley" in China, aiming to generate $1.2 billion in industrial output by 2000.[71]

China has also developed extensive state programs to help implement their goal of making the biotechnology and pharmaceutical industries a priority for growth. The Chinese Academy of Sciences has provided $20 million for 40 research projects in biomedicine for the past five years.[72] The projects have aided in the development of hepatitis B vaccines, interleukin-2, interferon alpha, and other specialist products.[73] In addition, China's State Science and Technology Commission (hereinafter SSTC) is responsible for the analysis of science and technology's role in society and for general management and coordination among various ministries and agencies.[74] The SSTC comprises six programs

66. *Development of Biomedicine in China*, Marketletter, London, Sept. 8, 1997.

67. *Id.*

68. Andrew Beckman, *Biomed & Biotech New Business Opportunities in China* (PRC), Biomedical Market Newsl., Apr. 1, 1996.

69. Dan Gallagher, China Offering Biotech Firms Big Opportunities, San Diego Daily Transcript, June 17, 1997 at A1.

70. *China to Focus on Biotech*, Biotechnology Newswatch, Jan. 20, 1997.

71. *Biotech Gets Top Priority in Zhangjiang*, Biotechnology Newswatch, Nov. 4, 1996.

72. *Development of Biomedicine in China*, Marketletter, London, Sept/ 8, 1997.

73. *Id.*

74. Beckman, *supra* note 68.

which support biomed/biotech development and commercialization. The first program is entitled China's Key Technologies R&D Program, which is organized in five-year time blocks.[75] By 1991, China had established 74 national key labs in higher education and research institutes. The following five-year plan (1991-1995) set goals in the biomed/biotech field to develop new biochemical reagents, and genetically engineered vaccines.[76]

The second program under the SSTC is entitled the "863" program because it was announced by Deng Xiao Ping in March 1986, listing biotech as one of seven targeted areas. This program channels most governmental funding for biotech in China, focusing primarily on the genetic engineering of animals and plants for high yield and quantity, the research and development of new medicines, vaccines and gene therapies, and protein engineering for food industries.[77]

In addition, China's National Center for Biotechnology Development administers a RMB 7.4 million annual budget for biotechnology under the SSTC.[78] Roughly 32% of that budget is devoted to pharmaceutical research, 8% for protein engineering research, 20% for commercialization, and 32% for agricultural research.[79] Foreign partnerships are also allowed to compete for funding in this program.

The SSTC's Torch program, established in 1988, aims to commercialize, industrialize, and globalize China's new technologies.[80] The biotech component of this program has focused on biopharmaceutical products for the creation of vaccines like hepatitis B, and anti tumor drugs.[81] The Torch program also provides contacts for foreign companies interested in joint ventures and offers incentives to investors in the 52 high tech zones that it has established across China.[82]

The Spark program was established in 1985 and has encouraged economic development in the rural areas of China through the application of science and technology.[83] Spark grants loan packages and has a development center under the SSTC which matches proposals with grants and loans.[84] Because this program focuses on biotech outside the field of medicine in areas like bioagriculture, grain production, animal

75. *Id.*
76. *Id.*
77. *Id.*
78. *Id.*
79. Beckman, *supra* note 68.
80. *Id.*
81. *Id.*
82. *Id.*
83. *Id.*
84. *Id.*

husbandry, and storage technology,[85] it has been particularly important in meeting the nutritional needs of China's approximately 1.2 billion people.

China's last program under the SSTC is the National Natural Science Foundation (hereinafter NNSFC), which promotes basic research in all science and technology. In 1993, the NNSFC had a total budget of $28 million, 14% of which was devoted to clinical medical sciences.[86] The NNSFC also launched a national genome project as part of its contribution to international genome project in 1993.[87]

Under all six of these programs, researchers submit their own projects to compete for funds allocated toward designated fields. These researchers are also expected to find external funding to supplement the slight decrease in governmental funding. China eventually plans to make external sources, such as international foundations and private firms bear the majority of financial responsibility and severely decrease government financing.[88] While the absence of governmental financing may lessen the government's control in determining the types of research conducted, many private companies who bear the total fiscal cost without the benefit of total control will likely look elsewhere for business. Therefore, if China follows through with its plans to completely cut government funding for biotechnology, and yet maintain restrictions on the type of biotech to be produced, it may be driving away the very industry it sought to create. The author is not suggesting, however, that the biotechnology industry be entirely unregulated by the government. Rather, until the industry is fully developed, China is in need of a balance between governmental and private control.

In addition, China hosts 120 domestic biotech companies which commit only a small portion of funding to research.[89] Most of these companies rely on results published by the Chinese research community and foreign sources to produce the scientific portion of their products. Moreover, the Chinese government's attempts at transforming the economy into a market system have created special government financing programs for commercially viable products to work in cooperation with a biotech company.[90] Thus, the government may transform research institutions into private labs that do work only on the products contracted

85. *Id.*

86. *Id.*

87. *China Enters Genome Research*, BIOTECHNOLOGY BUS. NEWS, Sept. 24, 1993. A genome is the complete set of haploid chromosome in an organism.

88. Beckman, *supra* note 68.

89. *Id.*

90. *Id.*

for with the biotech companies. While this system may create immediate profits since it focuses only on commercially viable products, it may defeat the purpose of an applied research system. The special government financing may also relegate China to simply producing products already known to be profitable, which likely stem from a foreign source, instead of being at the center of the development process and originating these products.

A. Foreign Firm Involvement with China's Biotech Industry

In the early to mid 1990's, foreign firms began to envision enormous investment opportunities in China for the biotechnological production of drugs, food and chemicals. By 1994, analysts were predicting that the market for medical technology products in China would grow three to four times faster than industrialized countries.[91] The same numbers were again forecasted for the years 1997-1999.[92] In 1996, China's medical technology market grew 28%, making it the fastest growing market in the world.[93] As a result of this positive financial outlook, and despite fears regarding adequate intellectual property protection, the U.S., Europe and Japan have been competing vigorously for investment opportunities in China.[94]

The business device employed by foreign firms in China is almost exclusively a joint venture. The remainder of foreign-owned enterprises that choose not to pursue joint ventures in China, but still want a share of the Chinese market, will ordinarily attempt to launch their own products there. Many firms from the U.S., Europe and Japan have engaged in joint ventures and have decided to move their clinical trials, R&D, and manufacturing capacity overseas to avoid delays and to be near the markets where they first introduce their products.[95] Foreign companies feel that these business relationships can prove beneficial by lowering research expenses, facility and manpower costs, and absorbing more advanced Chinese technology.[96] A few private companies have contracted projects with Chinese institutions to take advantage of transgenic plant technology advances achieved with the aid of international cooperation.[97] In addition, foreign biomed/biotech firms often view China as an

91. *Asia Fastest Growing Market*, BIOCHEMICAL MARKET NEWSL. Jan. 1, 1994.
92. *Id.*
93. *Market Research Studies: Expert market Devises Improving 1997 Global Market*, BIOMEDICAL MARKET NEWSL., Apr. 30, 1997.
94. *Id.*
95. *Id.*
96. Beckman, *supra*, note 68.
97. *Id.*

inexpensive place to conduct laborious processes which do not involve the transfer of their newest technology.[98]

The transfer of mainly older technology reduces some of the foreign companies' fears over intellectual property protection. Furthermore, conducting research with Chinese partners can facilitate a firm's product entrance into the Chinese market since many of the partners have relationships with the Ministry of Health.[99] Similarly, complaints lodged with the local government from a joint venture are ordinarily acted upon with more vigor than those from purely foreign companies. Local favoritism to joint ventures occurs because the Chinese partner will typically have a relationship with various governmental agencies, whereas a foreign-owned enterprise likely has no ties to China at all.

While the business opportunities in Chinese biotechnology appear endless, many Westerners warn that foreign firms need to be careful because the political system is not fully developed in China. For example, one U.S. entrepreneur involved in the biomed/biotech industry was shocked to learn that one of his Chinese clients was forced to register with the police within 30 days if that person wanted to use the Internet or other online services.[100] Moreover, a company may have problems getting its hard currency out of China once it has been converted into local Renminbi.[101] Another concern regarding Chinese joint ventures is that since local manufacturers have not yet constructed high-tech machines capable of producing enzymes and similar biotech materials, this high cost equipment must be imported from the U.S. or Japan.[102] After considering importation, transportation and administration costs, coupled with the frustration incurred from cultural clashes, setting up a joint venture in China does not come without a price. However, establishing a joint venture in China can nonetheless be a very lucrative business. Balancing the total expenses against low labor costs, beneficial tax credits, and favorable regulatory practices generally results in increased profit margins.

1. Sample Biotech Joint Ventures in China

In 1993, Merck, a multinational pharmaceutical company that uses biotechnology, inaugurated a high-tech manufacturing plant in Beijing

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98. *Id.*

99. *Id.*

100. David Anast, *Don't Throw our Chines Clients in Jail using the Interest is not a Crime*, BIOMEDICAL MARKET NEWSL., Feb. 1, 1996.

101. *New Company Aims to Bridge the Gap between East and West*, BIOTECHNOLOGY BUS. NEWS, June 3, 1994, at 13.

102. Beckman, *supra*, note 68.

to produce its hepatitis B vaccine.[103] The joint Sino-American project sought to initiate Chinese production of Merck's HB Vax II to enable the country to fight one of its largest public health threats.[104] The factory was built in collaboration with China's National Vaccine and Serum Institute under the Ministry of Public Health and is able to produce 20 million doses of anti-hepatitis vaccine.[105] Merck also established a second manufacturing plant in the southern city of Shenzhen in 1994.[106]

More recently, in 1996, the French genetic research company Genset established a joint venture in Beijing with the Chinese Academy of Medical Sciences and Tang Freres, a French trading firm that specializes in Chinese medical and pharmaceutical fields.[107] The objective of the joint venture is to collect DNA from related and unrelated individuals affected with common diseases, conduct gene discovery research on such DNA in collaboration with Genset, and eventually market products based on these discoveries in China.[108] Genset is engaged in the systematic and comprehensive analysis of the human genome to identify and patent genes. Genset then applies its genomics technology to both discover drugs for the treatment of diseases and to enter into strategic partnerships with pharmaceutical companies for the development and marketing of these drugs. Genset has targeted such ailments as prostate cancer, schizophrenia, osteoporosis, psoriasis, and hypertension. Upon the creation of this joint venture, Genset's president remarked, ". . .it provides us with access to highly-characterized samples representing a wide range of diseases from the largest population in the world. The immense resources of China in medical and clinical research are an ideal complement for Genset large-scale technology."[109] Therefore, by the creation of this joint venture, Genset clearly regards China as the proverbial 'field of dreams' in the futuristic realm of biotechnology.

Similarly, in 1997, Japan's Kirin Brewery Co. and China's Shanghai Kunpeng Investment Co. agreed to set up a joint venture in Shanghai to produce and market two drugs.[110] The first drug, Espo, will be used to treat renal anemia and the second drug, Gran, is a granulocyte colony stimulating factor. Kirin had previously been exporting the drugs to Beijing, Shanghai, and Guangzhou through its marketing base in Hong

103. *Merck opens hepatitis B plant*, BIOTECHNOLOGY BUS. NEWS, Oct. 21, 1993, at 9.
104. *Id.*
105. *Id.*
106. *Id.*
107. *Genset and Chinese Academy to Enter Joint Venture for Genomics*, WORLDWIDE BIOTECH, Dec. 1, 1996.
108. *Id.*
109. *Id.*
110. *Kirin in Shanghai Venture*, BIOTECHNOLOGY NEWSWATCH, June 2, 1997, at 6.

Kong. Now, however, the joint venture also plans to construct a basic research laboratory and a drug manufacturing facility for herbal medicines by 2003.[111]

Thus, by establishing joint ventures in China, foreign firms are acknowledging that both the immense size of the Chinese market and the capability of the preexisting Chinese medical facilities have created favorable arenas in which to launch their biomed/biotech products. On the opposite side of the bargaining table, China has been able to absorb numerous quantities of foreign technology, insights onto foreign expertise, and has received billions in foreign investment by forming joint ventures. Furthermore, the profits generated by the biotech industry will help fuel the Chinese economy and thereby contribute to an increased standard of living.

2. *Foreign use of Chinese Herbs to Produce New Drugs*

An interesting twist on foreign business relations with China has occurred through the increasing application of biotechnological processes on plants traditionally used in Chinese medicine to produce new drugs. Thus, herbal medicines originated by the Chinese are now being adapted through biotechnology to produce drugs capable of fighting various diseases. Unless the Chinese institute formal agreements that ensure adequate compensation for the use of their flora and fauna, foreign firms are likely to exploit China's natural habitat without fairly distributing any of the profits that have been accrued from the new biopharmaceuticals. The foreign use of Chinese plants to produce biopharmaceuticals underscores China's momentary failure to commercialize its own products, export its technology into the Western world, and to bring in developing Western technology for its own market. To date, China has acknowledged some of these failures by constructing joint ventures with foreign firms so that they can not only reap a share of the profits from the use of their plant/animal life but also gain an insight onto the technology employed to produce the new drugs.

For example, a joint venture was established by Global Pharm Ltd, a Bermuda based company, with Northeast No. 6 Pharmaceutical Factory in Shen Yang, China.[112] Global Pharm began its operations in 1995 and has sought to expand the market for Chinese government approved human-use pharmaceuticals. The company has also planned to select and acquire unrecognized Chinese pharmaceuticals for development in

111. *Id.*

112. *T Cell looks to China,* BIOTECHNOLOGY BUS. NEWS, June 23, 1995, at 7.

other territories.[113] Like many foreign companies, Global Pharm chose China for access to its large, emerging market opportunities in therapeutic products, as well as access to new product candidates for development outside China. The first product to be marketed by the venture is for the treatment of hypertension and microcirculation disorders.[114] The drug is a synthetic copy of the active ingredient found in a Chinese herb.[115]

The British firm Xenova has signed drug discovery agreements with the Institute of Medicinal Plant Development (hereinafter IMPLAD) and the Institute of Botany, both in the Peoples Republic of China.[116] The agreement establishes that IMPLAD will supply plant extracts and the Institute of Botany will supply a combination of plant extracts and phytochemicals to Xenova. The British firm will then run screening tests to identify potential drug activities against illnesses such as cancer, cardiovascular disease, and immune-inflammatory disorders.[117] Thus, Xenova uses its biotechnologies to formulate new drugs from natural sources. The arrangement further provides that Xenova will have marketing rights outside China for any therapeutics discovered, and China will both retain exclusive internal marketing rights and receive royalties on Xenova's sales.[118]

In the early 1980's, UCLA biochemists received several ancient lotus seeds from the Beijing Institute of Botany that were recovered from a lake in Pulantien, China.[119] The UCLA scientists have since discovered a powerful genetic system in the seeds to delay its aging.[120] Upon examining the lotus embryos, the scientists found a protein repair enzyme which limits the accumulation of damaged proteins and helps the plant adapt to environmental stresses.[121] The enzyme, known as MT, is now being employed on longevity experiments with mice.[122]

For the most part, China has been able to control the foreign manipulation of traditional Chinese herbs by either forming joint ventures or contracting for a share of the profits derived from foreign biomedical

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113. *Id.*

114. *Id.*

115. *Id.*

116. *Xenova looks at Chinese Medicinal Plants for New Drugs*, GENETIC TECH. NEWS TECH. INSIGHTS, INC, Dec. 1, 1992.

117. *Id.*

118. *Id.*

119. *After Thousand-Year Sleep, Lotus Sprouts Chemistry of Longevity Theories*, BIOTECHNOLOGY NEWSWATCH, Jan.1, 1996, at 1.

120. *Id.*

121. *Id.*

122. *Id.*

enterprises. Once the industry has a few years to grow, China may be able to exclusively transform materials from their natural habitat into new pharmaceuticals without the need for any foreign control. If China can amass enough capital, establish strong research teams, and produce qualified economists, the only remaining foreign component that is required to construct biopharmaceuticals is high tech machinery.

B. The Effect of the Reunification with Hong Kong on China's Biotech Industry

In the late 1980's, biotechnology was identified as one of the major areas in which new profitable business opportunities could be generated in Hong Kong. Shortly thereafter, the Hong Kong Institute of Biotechnology (hereinafter HKIB) emerged on the shore of Tolo Harbor as a joint venture operation with a major U.S. pharmaceutical company, Syntex Corporation, for the discovery of novel therapeutic agents based on Chinese herbal medicines.[123] The joint venture had the express task of trying to merge ancient Chinese remedies with Western technology to find novel drugs to cure or treat twentieth century diseases.[124] Accordingly, the institute has signed an agreement with a Chinese research facility to internationally market a compound discovered in China which may help to treat cancer patients.[125] More importantly, however, the founders of HKIB viewed its formation as a link to biotechnology bases in Asia.[126]

Besides HKIB's major project, some of China's leading scientists in genetic engineering, together with a third group of scientists in Houston, are collaborating on a project headed by HKIB's founding director. The group seeks to develop new drugs to combat neurological disorders such as epilepsy, Alzheimer's disease, Parkinson's disease, depression and substance abuse.[127] A major part of the research includes the transfer of human neurological genes into mouse cells to construct specific genetic engineered cell lines.[128] The scientists hope that the cloned cells will be able to shed light on the molecular basis of many brain functions. They also hope that the cells will be useful for the discovery of new pharmaceutical agents against a number of brain and cardiovascular diseases.

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123. *Jonathan Lange, Brainstorming the Brain Cells*, WORLDWIDE BIOTECH, Sept. 1, 1992.
124. *Id.*
125. *Id.*
126. *Id.*
127. *Id.*
128. *Id.*

Based on the success of HKIB and similar companies, researchers at the Massachusetts Institute of Technology announced a study in early 1997 that Hong Kong would be a major player in the field of biopharmaceuticals produced from traditional Chinese medicines.[129] The researchers at MIT believed that Hong Kong's success would be driven by the historical acceptance of these medicines and the extensive data which has been collected about them.[130] They cited that another important advantage Hong Kong has over its rivals is its close proximity to China.[131] The close link between the territory and the mainland has enabled local companies to draw on the expansive breadth of knowledge that the Chinese have amassed over the centuries regarding the proper use of their medicinal plants.

A second event in early 1997 made Hong Kong a focus site for biotechnology. The Beijing Institute of Developmental Biology at the Chinese Academy of Sciences decided to collaborate with the University of Hong Kong to combine China's animal husbandry expertise with Hong Kong's research skills and equipment.[132] The goal of the collaboration was the development of improved gene targeting methods in creating transgenic animals.[133] China had been genetically altering pigs and goats to produce drugs from their milk and sought to increase the scope of their research capabilities by forming the agreement.[134]

Finally, on the evening of June 30, 1997, the world watched the official ceremonies and fireworks celebrations that marked Hong Kong's return to Chinese control. Although there has been much speculation on the future of Hong Kong, the Chinese government has promised to maintain 'one country, two systems' for the next fifty years. In fact, China has erected enormous advertising billboards on the southern border between Hong Kong and Shenzhen which emphatically announce that 'Hong Kong will have a more beautiful future.' The same slogan can even be glimpsed on t-shirts sold to tourists in the Temple Street night market.

Although there are many skeptics on China's ability to economically handle Hong Kong, the realm of biotechnology appears more secure. Since China sought to absorb Hong Kong's biomedical research capabilities before the handover occurred, and since China is intent on

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129. *Biotechnology Profile: A New industry Mushrooms*, HONG KONG INDUSTRIALIST, May 1, 1997.

130. *Id.*

131. *Id.*

132. *China, Hong Kong to Collaborate*, BIOTECHNOLOGY NEWSWATCH, Mar. 17, 1997.

133. *Id.*

134. *Id.*

the success of its own biotech industry, it is likely that the Chinese government will attempt to properly maintain Hong Kong's businesses and research facilities. Moreover, the Chinese will increasingly rely upon Hong Kong's biotech facilities after the handover to support their own growing biotech industry. Although Shanghai will be a top contender for receiving imports, Hong Kong's port capabilities will ease China's former import hassles because once the technologies reach Hong Kong, they can be channeled into China with reduced customs procedures. China may also be able to learn from the structure of Hong Kong's more Western style biotech system while perfecting their own. Therefore, the biotech development that occurred in Hong Kong during the years preceding the handover will only benefit China's expanding system.

1. The Biotechnological Impact of the Bird Flu in Hong Kong

In the months following the handover, however, Hong Kong suffered from what has become popularly known as the "bird flu." Since the onset of the outbreak, there have been a total of eighteen patients diagnosed with the virus, six of whom have died.[135]Because Hong Kong and southern China have been historically characterized as breeding grounds for new strains of influenza, the avian virus spread fears of a worldwide epidemic.[136] As a result of these rising fears, the National Institutes of Health awarded Protein Sciences Corporation, a U.S. company, the vaccine contract in December 1997, after receiving an urgent request from Hong Kong.[137] By February 3, 1998, the biotechnology company successfully produced a genetically engineered vaccine to combat the virus.[138] Chief Executive Officer of Protein Sciences, Daniel D. Adams, commented, [Through the use of biotechnology] "it is now feasible to respond in a timely fashion to emerging new influenza virus strains and to decide on which strains to include in the annual flu vaccine much closer to the time the vaccine is needed."[139] Although Hong Kong required the aid of U.S. biotechnology companies in order to produce a vaccine for the current strain of avain virus, it is possible that in the future, Hong Kong will have the capacity from its own biotech companies to handle another outbreak. Because new strains of influenza

135. Marilyn Chase, *Flu Viruses HitHard As Researches Plan Their Next Defense*, WALL ST. J., Jan. 19, 1998, at B1.

136. Craig S. Smith, *Hong Kong Halts Live Chicken Imports From China Due To Avian Flu Virus*, WALL ST. J., Dec. 16, 1997, at B7.

137. *Emergency Human Vaccine Against Hong Kong H5N1 Influenza "Bird Flu" Developed by Connecticut Biotechnology Company* (visited Mar. 1, 1998) <http://www.proteinsciences.com>.

138. *Id.*

139. *Id.*

commonly occur in Hong Kong and Southern China[140] , the Chinese have an incentive to form biomedical companies which can quickly produce vaccines. These vaccines can also be used to prevent infection in animals and break the chain of transmission from animals to humans.[141] Since the current bird flu was able to spread among thousands of chickens before being discovered, subsequently requiring their mass slaughter,[142] Hong Kong has suffered a significant economic loss. If, in the future, China can focus its energies on establishing successful biotech companies, substantial economic loss caused by influenza could be prevented.

V. Conclusion

Based on China's stunning capabilities to not only transform an entire body of law, but also to shape a high tech industry within a mere decade, the Chinese will likely disarm the world in the coming years with its biomed/biotech industry. China has strategically recognized the need for foreign support in getting its biotech industry off the ground. Once the Chinese, however, gain the facilities to produce the high tech equipment required for the formation of biomedical materials, they will no longer have to wholly rely upon foreign investment. Moreover, the Chinese are host to an enormous array of naturally growing flora and fauna which is currently the fastest developing sector of biomedicine. When the standard of living increases in China, the Chinese will have the first opportunity to tap a market of 1.2+ billion people. The Chinese population, afflicted in large numbers with hepatitis B and other diseases due to malnutrition and unsanitary living conditions, will doubtlessly require the new pharmaceuticals that China is manufacturing. In addition, China will be able to market the new biopharmaceuticals globally. If the Chinese market their drugs at a favorable time, as the trend is now shifting to favor Eastern style medicine, China may be extremely successful in the biomedical field. While China's success admittedly hinges on many 'if's', the development of biotechnology in China has shown enormous growth in a very short period of time. As long as China can maintain a similar rate of growth in the next decade, then

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140. Smith, *supra* note 136.

141. *Emergency Human Vaccine Against Hong Kong H5N1 Influenza "Bird Flu" Developed by Connecticut Biotechnology Company* (visited Mar. 1, 1998) <http://www.proteinsciences.com>.

142. Peter Stein, *In Hong Kong, Chicken Slaughter Fails to Kill Fears*, Wall St. J., Jan. 5, 1998 at A17.

biotechnology may very well be the field that restores China to its former magnificence.

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