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Now the Wolf Has Indeed Come! Perspective on the patent Protection of Biotechnology Inventions in China

by

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INTRODUCTION

The patent system is designed to grant inventors and innovators exclusivity over their inventions for a limited period in exchange for public disclosure of their inventions. Patent is thus often taken as "a way of maximizing social welfare by providing incentives for inventors to increase the stock of applied technical knowledge in society (through protection) and discouraging inefficient redundancy of inventive effort (through disclosure)."[1]

Different jurisdictions may have different levels of rules, but their patent systems "share common principles."[2] In the United States, as embodied in the US Constitution, the purpose of the patent law is "to promote the Progress of . . . useful Arts, by securing for limited Times to. . .inventors the exclusive Right to their. . . Discoveries."[3] In the European Union, a similar tenet can be found:

> The primary purpose of the modern patent system is to promote technical innovation as the major factor of economic growth by encouraging inventive activity through rewarding inventors for their creative efforts. The patent system thus secures costly investment in research and development and industrial exploitation of research results. Simultaneously, the patent system encourages an early and beneficial dis-

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1. John S. Leibovitz, *Inventing a Nonexclusive Patent*, 111 YALE L.J. 2251, 2256 (2002).

2. Peter Drahos, *Biotechnology Patents, Markets and Morality*, 21 EIPR 441, 442 (1999).

3. U.S. CONST. art. I, § 8.

> semination of knowledge in the field of activity involved which, without such protection, might be kept secret.[4]

With the advent of each new technology, however, controversy over the monopoly as granted the inventors through the patent system has almost always arisen; "controversy over granting exclusive rights to new technologies is as old as the patent system itself."[5] The focal point of the controversy is regarding the best way to balance the interests of inventors, competitors and the general public.[6] The patenting of biotechnology inventions is no exception.

The problem which this monopolistic right presents was clearly exemplified in a recent dispute surrounding the pioneering technology of DNA chips. The technology involves both "hardware" (the chip technologies themselves) and "software" (the actual genes that dot the arrays), which can identify genes by getting them to bind onto a large array of sample sequences fixed to a surface.[7] Solely on the "software" side, the array on a 2.5-centimeter chip can contain some 40,000 sequences. As pointed out by Jeffrey Trent, head of a DNA array project at the National Genome Research Institute in Bethesda, Maryland, "if each spot on the array involves a gene that's patented, they have to get licences for each spot."[8] He further pointed out that the dispute "has the potential to limit access and availability of the technology."[9]

Heller and Eisenberg referred to cases like the above as the "tragedy of the anticommons," where "multiple owners each have a right to exclude others from a scare resource and no one has an effective privilege of use."[10] In such a case, ". . .a user needs access to multiple patented inputs to create a single useful product. Each upstream patent allows its owner to set up another tollbooth on the road to product development, adding to the cost and slowing the pace of downstream biomedical innovation."[11]

This situation is just one instance of the problems encountered concomitant with the patenting of biotechnology in the West but sufficiently indicative of the controversies arising therefrom. Now the interesting questions are how the issues are perceived in China and how the patent law interplays with the development of biotechnology inventions there. Predicated on the belief that answers to these ques-

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4. Commission White Paper for the European Council, com (88) 496 final SYN 159, October 17, 1988; O.J.C. 10/3 (1989), para.11, at 6.

5. *See* Leibovitz, *supra* note 1, at 2255.

6. *Id.*

7. Robert F. Service, *Will Patent Fights Hold DNA Chips Hostage?* 282 SCIENCE 397, 397 (1998).

8. *Id.*

9. *Id.*

10. Michael A. Heller and Rebecca S. Eisenberg, *Can Patent Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998).

11. *Id.* at 699.

tions and other relevant issues will help to strengthen our understanding in this fast growing area from a different perspective, this essay seeks to provide some illumination by overhauling the patenting of biotechnology inventions in China, as well as unearthing problems as may be presented by the patent system and identifying areas for improvement.

Following the introductory comments in this part, the second part of the essay examines the historical development of the patent law in China and shows the underlying motivations for each major development. The third part then looks at the development of the biotechnology industry in China. Next, the fourth part of the essay provides an overview of the patenting of biotechnology inventions in China.

Careful research into the literature available in China reveals that there is a dearth of such material addressing the inhibitive effects of the patent protection on science and innovation or on society at large. The question then follows; does this mean that those effects are non-existent? In addressing this question, several relevant case studies are conducted in the fifth part of the essay. These studies have revealed that the inhibitive effects of patents are prominent in China and will, more likely than not, become more severe in the future. In the West, there is no consistent solution to the problem but some scholars have proposed the doctrines of the experimental use exception and compulsory licensing.[12] Accepting the soundness of the two doctrines for the purpose of this essay, the sixth part then sets out to examine whether the Chinese Patent Law has effectively incorporated them in order to cope with the problem. And if not, what areas are there for improvement?

In a bid for its WTO membership, China has adopted a Western-style patent law. However, ever since then, the adverse social impact of the patent system has begun to emerge and with China's membership to the WTO accepted, the problem has become more acute. It is high time, this essay argues, that the Chinese government rethink its position on the patent protection of biotechnology inventions so that the public interest in any patent system can be adequately addressed.

12. *See, e.g.*, Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989); Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000); and Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and A Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623 (2001).

HISTORY OF THE CHINESE PATENT LAW

It is widely believed that the patent system originated in the practice of granting the privileges to merchants by various monarchs in Europe, especially in Venice, Italy during the Middle Ages. A similar practice could also be found some 2300 years ago in the Chinese Western Han dynasty when a royal monopoly over the production and trade of iron and salt was established.[13] It should be noted that while the practices in both Venice and China were monopolies, they were also much like patent systems. However, they were aimed at producing revenue rather than encouraging innovation. In this respect, they were not patents. The practice in Venice later evolved to such an extent that it was transformed legislatively to encourage innovation, which arguably resulted in the formulation of the modern patent system. But a patent system in China, in its modern resemblance, was never developed through legislation; to a large extent, this is due to the predominance of a penal code in the country's legislative history, the civil affairs being left to custom and usage, as will be discussed later.

The first statutory patent law in China was the Regulations to Promote Industrial Technology enacted by Emperor Guang Xui in 1898 in the late Qing dynasty in the course of the Bourgeois Democratic Reform Movement.[14] The Movement was led by Kang Youwei in a bid to reform the nation, but it was short-lived and failed in 1899. Consequently, the Regulations experienced a brief existence of less than two months.

The activity of passing a patent law did not stop thereafter in the late Qing dynasty. The infamous Opium War, which is almost always capable of serving as a fanfare to incite Chinese nationalism in modern times, imposed on the government a series of unfair bilateral and multilateral treaties. One was the Treaty of 1903 on navigation and commerce, which was imposed by the United States. The Treaty provided that China would afford patent protection for a limited term "to citizens of the United States on all their patents issued by the United States, in respect of articles, the sale of which is lawful in

13. CHENGSI ZHENG, CHINESE INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER LAW 51 (1987). For a lively debate on the propriety and legality of the monopoly between the Confucian scholars and the Chief Minister in the imperial Court, see *The Debate on Salt and Iron*, *in* CHINESE CIVILIZATION AND SOCIETY: A SOURCE BOOK 23-26 (Patricia Buckley Ebrey, ed., 1981).

14. ZHENG, *supra* note 13, at 52. Some believed that the first patent law was the Charter of Rewards on Invigoration of Industry and Art as adopted on July 12, *1889* in the late Qing dynasty. See http://www.isinolaw.com/jsp/ip/patent/PATENT_evolution.jsp?LangID=0 where Professor Chengsi Zheng is one of its resident consultants and where it is mysteriously stated that the first patent was granted in 1882, seven years before the adoption of the said law. Another source also stated without elaboration that the first patent law was enacted in *1889*. See the website of the US Embassy in China, *available at* http://www.usembassy-china.org.cn/ipr/patent.html.

China, which do not infringe on previous inventions of Chinese subjects, in the same manner as patents are to be issued to subjects of China."[15]

In spite of the above random development, before the Qing dynasty came to an end in 1911 marking the end of old China, there had been no major legislative events in respect to intellectual property throughout the country's long history. This may mislead one into thinking that China had never developed a well-organized legal system. In fact, long before America was discovered, China had already employed "law as an instrument for keeping the social order, for expanding the power base of the government," which "endured until 1911 as a fairly effective and stable system."[16] Arguably, the origin of law in China can be traced as far back as 2697 B.C. when Huang Di promulgated the orders regulating the conduct of his subjects. During the Tang dynasty (618-907 A.D.), the Tang Code, comprising over 500 articles, was a comprehensive and elaborate piece of legislation reputed for its precise measurement of punishments. It was imported by all the neighbouring lands: Central Asia, Korea, Japan and the countries of South-East Asia, an example being the Japanese Taiho Code, published in 701, which was closely modelled after it.[17] The Tang Code continued to develop in the succeeding dynasties with the ultimate Code of the last Qing dynasty (1644-1911).

However, the law was for the most part penal in nature and designed to maintain the dynasty and to protect the State from the people.[18] "The only purpose of the law was to prevent and to deter the commission of criminal acts."[19] Matters of the civil law, either ignored or receiving limited treatment under the criminal law, were left to custom and usage and mainly to private arbitration. Examined in this light, the lack of, or sporadic, development of statutory intellectual property law up until then becomes comprehensible.

With the overthrow of the Qing dynasty in 1911, the Republic of China was established and one year later, the government enacted the Interim Regulations on Awards for Devices (Creations) aimed at

15. Article 10 of the 1903 Treaty between the United States and China, as quoted in WILLIAM P. ALFORD, TO STEAL A BOOK IS AN ELEGANT OFFENSE: INTELLECTUAL PROPERTY LAW IN CHINESE CIVILIZATION 37-38 (1995).

16. PHILLIP M. CHEN, LAW AND JUSTICE: THE LEGAL SYSTEM IN CHINA 2400 B.C. TO 1960 A.D. 7 (1973).

17. JACQUES GARNETA, HISTORY OF CHINESE CIVILIZATION 289 (1982).

18. *Id.* at 11. Other scholars have believed that the Qing Code included a good body of stipulations about civil matters and that "those who assumed the formal court system of the Qing dealt little with civil matters were simply wrong." Kathryn Bernhardt & Philip Huang, *Civil Law in Qing and Republican China: The Issues*, *in* CIVIL LAW IN QING AND REPUBLICAN CHINA 4 (Kathryn Bernhardt & Philip C. C. Huang, eds., 1994). However, those scholars agreed that the Qing Code was administrative and penal in its original approach and intent. *See* Philip Huang, *Law and Magisterial Adjudication*, *in* BERNHARDT & HUANG 174 (1994).

19. CHEN, *supra* note 16, at 11-12.

protecting Chinese inventions. It was reported that since the passage of the Regulations, a total of 692 patents had been granted up until 1944.[20] In 1944, a patent law was prepared in its modern resemblance by the Guomingtang government in Chongqing: it was intended to offer patent protection both for the Chinese and for foreigners on the reciprocal basis. Chemicals, foods and pharmaceuticals were excluded from the patentable subject matter. It was decided that a patent must be worked within three years of the grant. After three years it would be subject to compulsory licensing. But, soon after its adoption in 1949, the Nationalist government was defeated by the Communist movement and fled to Taiwan. Few patents were granted under the law.[21] Overall, the effect of this piece of patent law in China was minimal.[22]

After the founding of the People's Republic of China ("PRC") in 1949, the Communists repealed all existing laws and regulations and in their place, the precepts of the Marxist economic system took hold.[23] The government enacted the Provisional Regulations on the Protection of Invention Rights and Patent[24] Rights of 1950, a "two-track" system modelled on the Soviet system. The system provided for either the issuance of certificates of invention to inventors or entities or for the granting of patents to inventors. The former gave recognition to persons or entities for their worthy inventions and tied the monetary rewards to the savings realized from their inventions but granted no other exclusive rights with the right to exploit and disseminate the inventions vested in the State. The latter granted the inventors patent rights in the modern sense, vesting the ownership in the inventors who enjoyed the control of the exploitation of the inventions. Under the Regulations, the term of protection could be anywhere from three to fifteen years as decided by the Commission of Finance and Economics. Further, foreigners were entitled to an invention certificate or a patent if they had an address in China.[25] However, the Regulations did not fare well. From 1953 to 1957, only six invention certificates and four patents were issued.[26]

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20. ZHENG, *supra* note 13, at 52.

21. *Id.*

22. *See* http://www.isinolaw.com/jsp/ip/patent/PATENT_evolution.jsp?LangID=0.

23. Brian Barron, *Chinese Patent Legislation in Cultural and Historical Perspective*, 6 INTELL. PROP. J. 313, 314 (1996).

24. The equivalence of "patent" in the Chinese language is "exclusivity," not "a letter open to the public" as understood in English.

25. Articles 6, 7, 9 & 18 of the Regulations of 1950.

26. Zongshun Tang, *The History of the Drafting of the Patent Law*, *in* INTELLECTUAL PROPERTY SYSTEM IN CHINA (Chuntian Liu, ed., Beijing: Patent Works Publishing Press, 1998) at 93. The first patent application was filed on October 20, 1950 and granted on April 1, 1953. The delay may have reflected either the uneasiness of the government granting a private right of exclusion to an individual or the priority of the state over the individual by postponing the patent application to the state affairs. The first Invention Certificate was issued for a popular process for making soda as

It may be naïve to believe that the Regulations were simply aimed at encouraging inventions.[27] On the one hand, indeed, the "two-track" system was focused on the implementation of the policy of national reconstruction by encouraging inventions. On the other hand, by recognizing the private ownership of intellectual creation, it also sought to appease the "anxieties of Chinese intellectuals and holders of substantial private property, whose participation was needed to rebuild the country."[28] But the notion of the private ownership of intellectual creation was anathema to the Socialists. Thus, the interesting question becomes; what rationale had underlain the adoption of the "two-track" system whereby the private ownership of intellectual creation was recognized? To answer this question, let us first look at the Socialist conception of intellectual creation.

In the socialist society where Marxism was adopted, it was widely accepted that intellectual creation or invention was a product based upon a repository of knowledge that belonged to all members of society and thus a product of the larger society.[29] Marx wrote in 1844:

> Even when I carry out scientific work, an activity which I can seldom conduct in direct association with other men, I perform a social. . . act. It is not only the material of my activity. . . which is given to me as a social product. My own existence is a social activity. For this reason, what I myself produce, I produce for society, and with the consciousness of acting as a social thing.[30]

Confucius, whose values and heritage underlay the ideology of Chinese society, said in a like manner, "I transmit rather than create; I believe in and love the Ancients."[31] The power of the past embodying originality and truth shows that the true owner of intellectual creation resides in the past; no later author may claim exclusive rights over it. Confucians showed disdain for profits as they argued that, "when profit is not emphasized, civilization flourishes and the customs of the people improve. . . To open the way for profit is to provide a ladder for the people to become criminals."[32] But the essence of intellectual property rights falls squarely within the pursuit of profits. Indeed, to Confucians, no one can be justified to exclude

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claimed by Dr. Debang Hou. The process had been industrially exploited as from 1943. *See* ZHENG, *supra* note 13, at 53.

27. Such belief was held by some. *See, e.g.*, http://www.isinolaw.com/jsp/ip/patent/patentevolution.jsp?LangID=0.

28. ALFORD, *supra* note 15, at 58.

29. *Id.* at 56-57.

30. KARL MARX, EARLY WRITING 157 (Thomas B. Bottomore, trans & ed. 1963).

31. THE ANALECTS OF CONFUCIUS, bk. 7, chp. 1 (1988).

32. KENNETH LEIBERTHAL, GOVERNING CHINA: FROM REVOLUTION THROUGH REFORM 5 (1995)

others from things essentially belonging to the omnipotent past; but true authors strive for enlightenment with moral reward.

Though neither Marx nor Confucius put forward a strong rationale for treating intellectual creation as a private ownership interest, both believed that the flow of ideas to the populace should be controlled and that this control was to be exercised by a very small group of people for the benefit of the whole society.[33] However, this weak and unclear rationale, if carried out further, was arguably a source of the creation of classes in the society while the ultimate goal of the Socialist was to create a classless society.

Then why did the Soviets adopt the "two-track" system and grant private property rights via patents to individuals whose inventions were regarded as the result of social activities, a system which was readily adopted by Communist China?

In the Soviet Union, the ideology of classical Marxism has been the foundation of the Soviet concepts of law as shaped by Lenin's *State of Revolution*. Lenin posited that during the transitional period of communist society, there is still law, though it is "bourgeois" law to a certain extent, and it is necessary to maintain the law to induce people to work for society:

> In the first phase of communist society (generally called socialism) "bourgeois law" is not abolished in its entirety, but only in part, only in proportion to the economic transformation so far attained, i.e., only in respect of the means of production. "Bourgeois law" recognizes them as the private property of separate individuals. Socialism converts them into common property. To that extent, and to that extent alone, does "bourgeois law" disappear. . .It is "defect", says Marx, but it is unavoidable during the first phase of communism; for if we are not to fall into utopianism, we cannot imagine that, having overthrown capitalism, people will at once learn to work for society without any standards of law; indeed, the abolition of capitalism does not immediately lay the economic foundation for such a change—and there is no other standard yet than that of "bourgeois law." To this extent, therefore, a form of state is still necessary.[34]

The Soviet "two-track" system embodies the co-existence of the "bourgeois" concept of the private ownership of intellectual creation with the "Socialist" ideology of common ownership; maybe, allowing the "bourgeois" patent in the initial period of the transition to communism whilst maintaining the "Socialist" invention certificate in

33. ALFORD, *supra* note 15, at 57.

34. VLADIMER ILYICH LENIN, *State and Revolution, in* SELECTED WORKS, VOL. VII 224 (1937).

the system would encourage people to invent for the society and ultimately achieve the replacement of the former by the latter.

As in the Soviet Union, during the transitional period of Communist China, law and "a form of state" were still needed to maintain social stability, to encourage the reconstruction of the country and ultimately to achieve the socialist common ownership:

> During the transitional period—from the establishment of the People's Republic to the completion of the building of the nation into a socialist society—the general role of the party and the state is the gradual realization of the socialist industrialization and the socialist transformation of agriculture and capitalist industry and commerce. Thus, the basic function of the civil law is designed to realize the national economic plan and *to advance the formation of the system of socialist ownership* (emphasis added).[35]

To carry out the goals, the "two-track" system of the Soviets undoubtedly was appealing to the Chinese leaders who had adopted the Soviet ideology as the state ideology and who likewise believed that as a temporary expediency, recognition of private property rights in the civil law, though capitalist in nature, was necessary in China's transitional period. Thus, it comes as no surprise that the system was applied there. However, the expected ultimate replacement of private ownership by common ownership and indeed, the inherent irreconcilable contradiction between the social nature of intellectual invention as entrenched in the ideology of the Socialist party and the controlling of such inventions through private ownership predestined the short-lived existence of the private ownership of intellectual creation in Communist China.

Indeed, beginning in 1953, China embarked on its planned economic programs under which its civil law was engineered to promote the transformation of private ownership into public ownership.[36] The Regulations of 1950 were replaced by the 1954 Provisional Regulations on Awards for Inventions, Technical Improvements, and Rationalization Proposals Concerning Production. The new Regulations placed emphasis on the awarding of invention certificates rather than patents and specified the amount of monetary rewards for invention certificate holders as tied to savings realized by the application of the inventions.[37] Though patent protection was not scrapped from the Regulations, the private ownership of intellectual creation was soon

35. CHEN, *supra* note 16, at 121.

36. *Id.* at 122.

37. Article 7 of the Regulations of 1954 includes a computing table for the amount of the monetary awards "according to the value saved in the twelve months after such invention, technical improvement or rationalization proposal is adopted." An English version of the Regulations can be found in ALBERT P. BLAUSTEIN, FUNDAMENTAL LEGAL DOCUMENTS OF COMMUNIST CHINA (1962).

after thrown into doubt with the vicissitude of the fate of the intellectuals.

In May and early June 1957, Chairman Mao invited intellectuals to help rectify the Party by offering criticisms under the "Hundred Flowers, Hundred Schools" Policy often dubbed the "Double Hundred" Policy. The criticisms offered exceeded the expectations and consequently the Party leaders initiated the Anti-Rightist Movement to strike back at those critics.[38] During the following Great Leap Forward of 1958-60, scientists and other intellectuals were pressured into pursuing an immediate, and what later proved to be unachievable, growth in industrial and agricultural productions. The failure of the Great Leap Forward prompted the launch of the Socialist Education Campaign in 1962, with the consequence that scientists and other intellectuals were blamed for placing their professional pursuits ahead of the Communist Party's objectives and "exiled" to work in the countryside or factories to be "re-educated" by farmers and factory workers.

Unsurprisingly, the following year of 1963 saw the official abolishment of the Regulations of 1950, which were supplanted in the same year by the Regulations to Encourage Inventions and the Regulations to Encourage Improvements in Technology. These two sets of Regulations struck the patent protection from the law: inventions and improvements in technology were to be the exclusive property of the State.[39] No property rights were to be granted inventors who were entitled only to "material" and "honorary" awards under the two Regulations, thereby replacing a "two-track" system with only a system of awards. Unfortunately, even those "material" and "honorary" awards were scrapped with the onset of the Cultural Revolution (1966-1975), which quickly put an end to the Regulations.

The anathema of the private ownership of intellectual creation in Communist China during the period is further illustrated by the following popular saying:

> Is it necessary for a steel worker to put his name on a steel ingot that he produces in the course of his duty? If not, why should a member of the intelligentsia enjoy the privilege of putting his name on what he produces?[40]

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38. CHEN, *supra* note 16, at 63-64.

39. Article 23 of the Regulations of 1963 provides that "All inventions are the property of the State; all enterprises (both state owned and collectives) are free to make use of them when they think fit." The Regulations no longer shared similarity with the Soviet "two-track" system in the sense that the latter allows the state to retain the title to the invention while the former virtually wipes out the rights vested either in the state or the inventor with the consequence that the invention has fallen into the public domain. *See* ZHENG, *supra* note 13, at 53.

40. As quoted in ALFORD, *supra* note 15, at 56.

It is not difficult to understand this change in Communist China concerning intellectual property rights if we bear in mind that the reason for granting the private property rights was based on the temporary expediency during the transitional period, but the ultimate goal was to annihilate private, therefore capitalist, ownership and to establish common ownership. As inscribed in the first Constitution put in place shortly after the seizing of power by the Communists in 1949, capitalist ownership was going to be "gradually replaced by the system of ownership by the whole people."[41]

With the Cultural Revolution coming to a real end significantly marked by the overthrow of the "Gangs of the Four" in 1976, China's new leadership under Deng Xiaoping put in place a program of "Four Modernizations" with its goal being China reaching world-class strength in agriculture, industry, science and technology, and national defense by the end of the century. Henceforth, China commenced its new "Long March" for economic and industrial development. In 1978, the government reissued the 1963 Regulations and a year later issued the Regulations for the Reward and Encouragement of Natural Sciences whereto the basic principles laid down in the 1963 Regulations were extended.

In 1979, the Chinese leadership made an "unprecedented decision" to open up China to foreign direct investment.[42] A credible legal framework was necessary to carry out the initiative. In the subsequent years, China promulgated a number of laws and acceded to many bilateral and multilateral treaties such as the United Nations Convention on Contracts for the International Sale of Goods.[43] Following five years' study, research and debate with the input of no less a personage than Deng Xiaoping,[44] 1984 saw the passage of the first patent law in modern China, "heralded, both at home and abroad, as signalling the dawn of a new era in Chinese economic and legal development."[45]

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41. PRC 1954 CONSTITUTION, art. 10.

42. STANLEY B. LUBMAN, BIRD IN A CAGE: LEGAL REFORM IN CHINA AFTER MAO 192 (1999).

43. *Id.*

44. *See* ALFORD, *supra* note 15, at 69. To pave the way for the 1984 Chinese Patent Law, China sent convoys of various backgrounds to the developed countries such as the United States and Germany and international bodies such as the WIPO to study and research their practices. The huge efforts poured into the legislation are evident from the following:

> "The full patent laws of some 35 jurisdictions were translated and those of more than 100 other nations summarized, while the legislation and practice of the Nationalist Chinese, both on the mainland prior to 1949 and on Taiwan, since, were carefully, if quietly, scrutinized, as was the experience of Hong Kong. Nor was attention solely directed externally, as the committee solicited the views of cadres in factories, scientific research institutes, universities and government agencies" (internal quotations omitted). *Id.*

45. *Id.* at 69. Article 20 of the 1993 Chinese Constitution provides that "The state promotes development of the natural and social sciences, disseminates scientific and

The 1984 Patent Law was promulgated in consonance with the government's pursuit of economic development and technology advancement and renovation. During its eight-year lifetime, whether those goals had been achieved could not be answered with any certainty. For the government citing statistics, i.e., that, within the eight years, over 284,000 applications were filed with over 40,000 applications from foreigners representing some 65 jurisdictions,[46] the success of the law was affirmed. However, further analysis of those figures has shown that two-thirds of the applications filed by the Chinese were for utility models and design patents which really involved low-level technology in contradistinction to those by foreigners over 80 percent of which were for invention patents.[47] In this sense, some commentator concluded that "with rare exceptions, Chinese enterprises have done little to generate their own technology worthy of advanced intellectual property rights."[48]

In the early 90's, the rampage of piracy of intellectual property in China especially in respect to computer software prompted the United States Trade Representative ("USTR") to initiate a Section 301 investigation of China's intellectual property system. Rounds of consultations soon followed between the two countries. On January 17, 1992, the Memorandum of Understanding[49] was concluded hours before the deadline set by US Ambassador Carla Hills for China to agree to revise its intellectual property laws or to face the imposition of hundreds of millions of dollars of punitive tariffs on Chinese goods imported by the United States.[50]

Pursuant to the Memorandum, the Amendments to the 1984 Patent Law were passed on September 4, 1992. The Amended Patent Law[51] broadened its scope of patentable subject matter to include

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technical knowledge, and commends and rewards achievements in scientific research as well as technological discoveries and inventions"; Article 47 states that "Citizens of the People's Republic of China have the freedom to engage in scientific research, literary and artistic creation and other cultural pursuits. The state encourages and assists creative endeavors conducive to the interests of the people that are made by citizens engaged in education, science, technology, literature, art and other cultural work."

46. Yuan Zhou, *Foreign Patent Filings Lag Behind Domestic Increase*, CHINA DAILY, April 12, 1992.

47. As extracted by Alford from the statistics compiled by the Planning Division of the General Management Department of the State Intellectual Property Office. *See* ALFORD, *supra* note 15, at 83.

48. *Id.* at 84.

49. The Memorandum of Understanding Between the Government of China and the Government of the United States of America on the Protection of Intellectual Property (hereinafter *the Memorandum*) *available at* http://www.mac.doc.gov/China/Agreements.htm.

50. The US Trade Representative, *2002 Special 301 Report*, *available at* http://www.ustr.gov/reports/2002/special301-306.htm.

51. The Amended Law took effect on January 1, 1993. The Amendments shall have no retroactive effect in relation to patent applications submitted before January 1, 1993 and patents granted theretofore (Article 69 of the Amended Patent Law & Article 96 of the Implementing Regulations for the Patent Law). However, the

chemicals, pharmaceuticals,[52] foodstuffs, beverages and flavourings.[53] It extended the term of the invention patent from 15 to 20 years as calculated from the date of filing the application; the term of the patent rights for utility models and designs was increased from five to ten years. The grounds for the granting of compulsory licences were narrowed, and the revised grounds were believed to be basically in conformity with the requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("the TRIPS Agreement").[54] Moreover, the post-granting revocation procedure was substituted for the pre-grant opposition procedure, thereby shortening the patent approval process.

The Amended Patent Law was commended as boding well for foreign investors. One commentator made the following remarks:

> In the case of its recent Amendments to the Patent Law, China merely is altering the tailoring of a suit it already has found quite comfortable to wear, at least from an economic perspective. On balance, the Amendments to the Patent Law should allow investors to act with more confidence in the turbulent waters of China's burgeoning commercial markets.[55]

Though China "has greatly improved the legal regime for protecting intellectual property,"[56] the Amended Patent Law did not keep pace with China's economic restructuring; vestige of the planned economy remained in the law such that state-owned enterprises could not transfer their patents without authorization from the superior State administration, thus necessitating further amendments to the Law.[57] In the meantime, amendments were also needed so as to bring the Chinese Patent Law more in line with the requirements of the TRIPS Agreement, thereby paving the way for China's accession

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Amendments shall have retroactive effect in relation to the procedures for revocation and invalidation of patents granted theretofore.

52. Pursuant to Article 2 of the *Memorandum*, pharmaceutical products which were granted patents in the US between 01/01/1986 and 01/01/1993 and which have not been marketed in China were granted patent-like administrative protection under *the Regulations on Pharmaceutical Administrative Protection*, promulgated by the State Pharmaceutical Administrative Bureau on December 19, 1992 and coming into force on 01/01/1993.

53. Xikai Wen, *History and Comments on the Legislation of China's Patent*, *in* CHUNTIAN LIU, *supra* note 26, at 115.

54. *Id.* at 115-116. *See also* Yin Xintian, *A Brief Introduction to The Patent Practice in China*, 9 DUKE J. COMP. & INT'L L. 253, 254 (1998), wherein it was argued that "The revised Chinese Patent Law is fully in line with the [TRIPS] requirements."

55. Laurence P. Harrington, *Recent Amendments to China's Patent Law: The Emperor's New Clothes*, 17 B.C. INT'L & COMP. L. REV. 337, 370 (1994).

56. The US Trade Representative, *2002 Special 301 Report*, *available at* http://www.ustr.gov/reports/2002/special301-306.htm.

57. *China to Revise Patent Law*, THE PEOPLE'S DAILY, January 19, 2000, *available at* http://fpeng.peopledaily.com.cn/200001/19/eng20000119N140.html.

to the WTO.[58] In addition, official sources reiterated the need for the amendments in strengthening the protection of patent rights and simplifying and accelerating the patent approval.[59]

It cannot be ignored that the rapid development of biotechnology in China has also galvanized the revision of the Chinese Patent Law. Biotechnology has provided huge opportunities to combat human diseases and China, as will be seen later, has set it as a national priority to search amongst its rich populous resources for genes responsible for diseases and for ways to block their effects. However, lack of patent protection for the genetic discoveries utilizing the unique and rich genetic resources of the Chinese population has caused concerns among Chinese scientists. Tan Jiazhen, President of the 1998 18th International Congress on Genetics held in Beijing, described by *Nature* as "a chief architect of the revival of genetics over the past twenty years,"[60] wrote a letter to the Chinese leaders in 1997 setting out the importance of patent protection to the country:

> A gene is a kind of wealth. If China does not get its own gene patents, then in the next century its biotechnology industry and in particular its pharmaceutical industry will be like "the Admiral of the Northern Fleet who saw all his ships capsize and sink beneath the waves."[61]

The erstwhile Chinese President Jiang Zemin quickly responded by saying, "If we are not concerned about a danger when it is far away, we will certainly have greater worries when it is near."[62]

The Amendments were made as of August 25, 2000. The Implementing Regulations of the Amended Patent Law ("the Implementing Regulations") were promulgated on June 15, 2001 and came into effect on July 1, 2001.

In the following discussion, I first examine the development of biotechnology in China and then in the next section, the patenting of biotechnology inventions under its current Patent Law.[63]

Biotechnology in China

Genetics is not a new discipline in China. Before the founding of the PRC in 1949, Chinese researchers had done some pioneering

58. *Id.*

59. Statement of Jiang Ying, Commissioner of the State Intellectual Property Office, delivered at Press Conference of News Office of the State Council on September 1, 2001, in Introduction to the Second Amendment to the Patent Law (compiled by the Chinese State Intellectual Property Office, Beijing: Intellectual Property Press, 2000).

60. David Dickson, *Back on Track: The Rebirth of Human Genetics in China*, 396 Nature 303, 305 (1998).

61. As quoted *id.* at 303.

62. *Id.*

63. The 2000 Chinese Patent Law (hereinafter *the Chinese Patent Law*).

work in the area.[64] Ruqi Li, a *Drosophila* geneticist, who had worked with T.H. Morgan at Columbia University in New York City, was one of such researchers who returned to China to contribute to its development of genetics. However, later events after the establishment of the PRC had hindered the further development of genetics there for a long time.

In the early 1950s, under its comprehensive pro-Soviet policy, China imported a number of Russian technical advisors to help rebuild the nation. With them were brought, under the name of "Michurinism," the ideas of the Russian Michurinist Trofim Lysenko who dismissed Mendelian genetics as "bourgeois ideology."[65] Soon after, Lysenkoism was formally endorsed as the official Party doctrine by the Chinese Communist Party ("CCP") in 1952 and the Western concept of genetics was henceforth banned.[66] As a result, the subject of genetics was purged from school textbooks, university courses and all research programs; "for about two generations of students, the subject [genetics] was not taught at all. 'Gene' was a bad word, a slogan of the bourgeoisie."[67]

In 1957, when the scientists were given the chance to voice their concerns publicly under the "Double Hundred" Policy, Lysenkoism had received unprecedented attacks from many scientists. The result was that the study of genetics was restored to some extent. The subsequent Anti-Rightist Movement, however, had immediately deprived those scientists of whatever little victory they may have previously claimed. The opportune establishment of the Institute of Genetics under the Chinese Academy of Sciences in 1959 following the expulsion of the Russian advisors may have signaled the leveling of the monopoly of Lysenkoism in Chinese science. But ironically, the Institute was essentially under the control of Lysenkoist-minded leaders and its first members "were all veteran Michurinists."[68] Though non-Michurinist biologists were gradually included beginning in the early 1960s, it "continued to display the legacy of Michurin biology into 1980s."[69] One may wonder why Lysenkoism had such a lingering effect in China as it did in the Soviet Union despite that it was somewhat discredited following the death of Sta-

64. *See* Dickson, *supra* note 60, at 303.

65. *Id.*

66. LAURENCE A. SCHNEIDER, BIOLOGY AND REVOLUTION IN TWENTIETH-CENTURY CHINA 117 (2003). It may not be quite accurate to say that Chinese science was "dominated" by Lysenko's ideas for two decades as said in Anonymous, *China's 'Eugenics' Law Still Disturbing Despite Relabelling*, 394 NATURE 707, 707 (1998) (Editorial). But it is certain that its "legacy" and lingering effect were clearly felt for that long or even longer.

67. Huanming Yang, *see* Dickson, *supra* note 60, at 303. Huanming Yang is a professor of genetics at Chinese Academy of Sciences and also director of the Academy's Human Genome Center in Beijing.

68. SCHNEIDER, *supra* note 66, at 188

69. *Id.*

lin in 1953.[70] In part, it is possible that its pragmatic approach toward science, i.e., that nature is subject to the will of humans, found particular appeal in Mao's regime, which was bent on pursuing immediate growth and accelerated development. In part also, the legacy of Lysenkoism was a "legacy of dogmatism, censorship, and political coercion,"[71] which was vigorously defended and maintained by its adherents to help to keep their high posts and dominions, thereby holding back the sounding of its death knell.

In a larger sense, this "legacy of dogmatism, censorship, and political coercion" had broadly permeated the CCP's policy for its treatment of the scientific community throughout the period. To this must be added the aforementioned persecution of the scientists and other intellectuals during the anti-Rightist Movement following the "Double Hundred" Policy and the launch of the Socialist Education Campaign following the failure of the Great Leap Forward. Under these circumstances, it is hard to imagine any meaningful development of science and technology including genetics. And indeed, the subsequent Cultural Revolution culminated in the virtual stoppage of the development of genetics.

The "Four Modernizations" promoted by the Chinese leader Deng Xiaoping marked the beginning of a new era of development for China's science and technology. It first began its agricultural gene research in the early 1980s. In the mid-1980s, biological technology was listed in the National High-Tech Development Program, also known as "the 863 Program."[72] In 1986, Deng, "anointed genetic engineering as one of seven technologies critical to economic growth."[73] In the following years, impressive achievements were made such as the implanting of virus-resistant genes in tomatoes and sweet peppers.[74]

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70. Indeed, "it took Stalin's successors eleven years to change their minds completely about the usefulness of [Lysenkoist] agrobiology." *See* DAVID JORAVSKY, THE LYSENKO AFFAIR 158 (1970). Though Khrushchev's resignation in 1964 had witnessed "broad advance" against Lysenkoism and Lysenko was dismissed from the directorship of the AS Institute of Genetics in the following year of 1965, the influence of Lysenkoism did not come to an end. In fact, it "is far from having been liquidated; nor has it lost its aggressiveness." ZHORES A. MEDVEDEV, THE RISE AND FALL OF T. D. LYSENKO 221-223, 240 (I. Michael Lerner, trans., 1969). Some of the reasons lie in its adherents' "unwillingness to relinquish the primitive collection of dogmas they have so firmly mastered and held for so long" and "unwilling[ness] to relinquish the high posts they had occupied for so long (by no means because of their high qualifications)." *Id.* at 240. For a comprehensive analysis, *see* Ch. 11, *id.*

71. SCHNEIDER, *supra* note 66, at 202.

72. *New Laws to Guide Nation's Gene Work*, CHINA DAILY, May 30, 2001, *available at* http://fpeng.peopledaily.com.cn/200105/30/eng20010530_71375.html (herein after *New Laws to Guide*).

73. David Stipp, *China's Biotech is Starting to Bloom*, FORTUNE, Sep. 2, 2002, *available at* http://www.fortune.com/fortune/technology/articles/0%2C15114%2C370081%2C00.html.

74. *Id.*

In the dawn of the new century, the government set its sights on an "innovation economy," encouraging closer links between research institutions and industry and endorsing the importance of high-tech to its economic prosperity.[75] In early 1998, China made research into the separation, cloning, structure and function of genes a top priority in its "863 Program."[76] In the same year, it became the only developing country to take a role in sequencing the human genome under the International Human Genome Project ("HGP").[77]

With the proven mettle in sequencing, the successes in plant transgenics and strong government support, Chinese researchers launched a whole range of programs ranging from stem-cell research, to research for genes that underlie diseases and for ways to block their effects, research which has become a national priority.[78]

Now, the Chinese National Human Genome Center ("CHGC") Shanghai has identified hundreds of full-length cDNAs. CHGCs in Beijing and Shanghai are focusing on genes related to liver cancer, nasopharyngeal cancer, esophageal cancer and leukemia. Meanwhile, the Beijing Genome Institute ("BGI") and CHGC cooperate to identify single-nucleotide polymorphisms (SNPs)[79] from the Chinese population.

China possesses unique genetic resources. There are 56 minority groups, many of which live in the remote isolated border regions such as Tibet and XinJiang. Geographical isolation has allowed each group to maintain its cultural and genetic identity over thousands of years. Inbreeding has resulted in a homogeneous genetic makeup within each group and a lack of emigration/immigration makes it easy to construct large family pedigrees.[80] This unique resource offers huge potential for the study of genetic diseases through linkage analysis in large numbers of families. In a sense, China has surpassed Iceland and Finland, which have become hot spots for mapping the chromosomal location of genes predisposing to disease. As said by Lin He, "We have several Icelands and several Finlands [in China]."[81]

A *Fortune* article fully testified to the achievement of the Chinese biomedical and bioagricultural research, making the following comment:

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75. Tian Suewen, *As Government Sets Sights on An 'Innovation Economy'*, 401 NATURE 312 (1999).

76. *Id.*

77. David Cyranoski, *A Great Leap Forward*, 410 NATURE 10, 10 (2001).

78. *Id.*

79. SNPs are markers of genetic variability which aid the research for the genes that predispose humans to complex diseases such as cancer and psychiatric disorders.

80. *See* Cyranoski, *supra* note 77, at 10.

81. As quoted in Cyranoski, *id* at 11. Lin He works for the project in Shanghai Jiao Tong University coordinating the bank for blood, tumour and cerebrospinal fluid samples collected from the populations across China.

> Call it a great leapfrog forward: Chinese medicine is jumping into the genomics era while still at one with remedies like bear bile and dried sea horse. Barely three years old, the Beijing Genomics Institute has already emerged as a world leader—it recently stunned Western scientists by decoding the rice genome in a matter of months. Last year a Beijing team grew dog-bladder tissue on a mouse's back, a prelude to generating human tissue. In Changsha, a city in central China, researchers claim to have cloned dozens of human embryos as sources of stem cells, which promise to rejuvenate failing organs[82]—an apparent world first, the Wall Street Journal reported in March.[83]

China has been very successful in the genetic engineering of plants. China has also made remarkable achievements in pest and disease resistance, quality improvement, and herbicide resistance. In 1988, a variety of bioengineered tobacco resistant to the tobacco mosaic virus was released in China's Liaoning Province, thereby making it the first country ever in the world to grow a genetically engineered crop commercially.[84] The official report indicated that by the end of 1996, Chinese scientists had been conducting research on 47 transgenic plant species, involving 103 kinds of genes.[85] In 2001, Chinese officials announced plans to quintuple government funding of agro-biotechnology research to $500 million p.a. by the year 2005, which would exceed the US government spending if met.[86] In 2002, China became a leading transgenic planting country following the United States, Canada, Brazil and Argentina with a total cultivation area exceeding 2.1 million hectares for transgenic crops.[87]

China was also reported to have reached or even surpassed the world's most advanced levels in transgenic animal cloning techniques.[88] Goats have been successfully cloned by adopting the fetus

82. *China Succeeds in Duplicating Organ from Stem Cell*, XINHUANET, *available at* http://www.edu.cn/20011119/3010745.shtml. According to the article, gastrointestinal organs by culturing stem cells has been successfully regenerated and duplicated, which breakthrough in the study of human organ duplication may prove to be a valuable way of treating gastrointestinal diseases via regenerating gastric and intestinal mucosa tissues.

83. *See* Stipp, *supra* note 73

84. Carl E. Pray, *Public and Private Collaboration on Plant Biotechnology in China*, 2 AGBIOFORUM 48, 49 (1999), *available at* http://www.agbioforum.org/v2n1/v2n1a09-pray.pdf.

85. *See New Laws to Guide*, *supra* note 72.

86. *See* Stipp, *supra* note 73.

87. Tom Clarke, *China Leads GM Revolution: Government Funding Puts Chinese Plant Biotechnology Second Only to US*, NATURE, 25 January, 2002, *available at* http://www.nature.com/nsu/020121/020121-13.html. Also, *China Becomes One of the Top Transgenic Planting Countries*, THE PEOPLE'S DAILY, December 7, 2003, *available at* http://ce.cei.gov.cn/enew/new_h2/fa00hl71.htm.

88. *See, e.g.*, Yang Ruoqian, *Second Cloned Cow was Born in Shandong*, THE PEOPLE'S DAILY, November 8, 2001, *available at* http://www.edu.cn/20011108/3008916

somatic cell of the transgenic goat and adult somatic cell.[89] "The rate of success is 10-20 times as much as Sheep Dolly," said a report as released by the Chinese Ministry of Science and Technology.[90] The report also revealed that China had bred pigs, rabbits and sheep using growth hormone (GH) transfer and that the general rate of external source gene introduction into the animals was 2.1 percent, reaching the world's advanced level.[91]

In the area of human disease treatment, China is the first country to locate and clone the gene causing high-frequency nerve deafness and some genes causing hereditary diseases.[92] Currently there are already 150 types of biological pharmaceuticals in the process of clinical research.

If this trend were to continue, it may be justifiable to make some prediction for the future:

> Much sooner, though, the impact of Chinese science could make itself felt. U.S. companies and universities may well find themselves seeking access to cutting-edge Chinese biotech in drugs, agriculture, and other fields, rather than the other way around.[93]

The question remains, however, whether beneath these achievements, there are problems, real or potential, which may hinder the further development of biotechnology in China. Arguably, the present government policy and generous funding and grants for research should promote the development of biotechnology. However, the present regime may also impede the commercialization of inventions as it lacks incentives to tie research to commercialization.[94] The main problem regarding commercialization, though, lies in the dearth of venture capital ("VC") in China. Some of the regulatory barriers to foreign investment have been removed by the government, but both overseas and home-grown VCs still lack good "exit strategies" for cashing out their investments in the Chinese startups.[95] This is a major hurdle remaining for the much needed VCs. Funding by other means is likewise problematic; insofar as funding from the Chinese commercial banks is concerned, it is often subject to political leverage

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.shtml; *China's Second Cloned Calf Doing Well*, XINHUANET, January 25, 2002, *available at* http://www.edu.cn/20020125/3018727.shtml.

89. *China Clones Scores of Plants, Pigs, Sheep, Rabbits, Cows*, THE PEOPLE'S DAILY, May 30, 2001, *available at* http://www.china.org.cn/e-15/15-3-b/15-3-b-247.htm.

90. The report is entitled the "Present Status of Chinese High-Tech Agriculture and its Goal during the 10th Five-Year Plan (2001-05)." *Id.*

91. *Id.*

92. *China Rapidly Developing Biotechnology & Bioindustry*, THE PEOPLE'S DAILY, January 4, 2003, *available at* http://english.peopledaily.com.cn/200301/04/eng20030104109535.shtml.

93. *See* Stipp, *supra* note 73.

94. *See* Cyranoski, *supra* note 77, at 12.

95. *See* Stipp, *supra* note 73.

and the opaqueness in the banks' decisions may further baffle the progress of commercialization.[96] Seemingly, whilst the government encourages academic researchers to capitalize on their discoveries and try their hands at business, it needs to do more.

It is not within the scope of this essay to further address the above problem. What is of our concern here is whether there exists the legal environment in China that would promote the development of the biotechnology industry. To answer this question, we will first explore the patent protection of biotechnology inventions under the Chinese Patent Law and then discuss whether the problems relating to the patent system that are acute in the West are equally existent in China. Also, we will examine whether the two solutions proposed to solve the problems encountered in the West arising from the patenting of the biotechnology inventions (i.e., experimental use exemption and compulsory licensing) are likewise applicable in China.

PATENTING OF BIOTECHNOLOGY INVENTIONS

For a patent to be issued, an invention must fall within the ambit of the statutory subject matter; satisfy the legal requirements of "novelty," "inventiveness" and "practical applicability"[97]; and be so disclosed as to be "enabling."[98] Now let us examine each of the aforementioned elements.

A. The Statutory Patentable Subject Matter

Article 25 of the Chinese Patent Law 2000 excludes a list of subject matter from patent protection. This list includes the following:

(1) scientific discoveries;
(2) rules and methods for mental activities;
(3) methods for the diagnosis or for the treatment of diseases;
(4) animal and plant varieties;
(5) substances obtained by means of nuclear transformation.

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96. Funding from the Chinese banks can be a nightmare, which was well illustrated by the following five steps as taken by one Beijing-based entrepreneur in procuring a loan to finance his business of exporting Peking ducks: "First, he uses his business and social contacts to find a bank that will consider having him as a customer. Then he wines and dines bank executives. Next he provides extensive information to the credit committee. Then he woos a low-ranking branch loan officer. 'Some officers may even ask [me] to buy a car or an apartment [for them],' he notes. Then he has to find a firm that will deposit money in the bank, for a fee, as collateral for his loan. Separately, he must pay a firm to provide a guarantee. All this is for a one-year loan, 'and you have to worry about repayment by the end of the first half." SUPACHAI PANITCHPAKDI & MARK L. CLIFFORD, CHINA AND THE WTO, CHANGING CHINA, CHANGING WORLD TRADE (John Wiley & Sons (Asia) Pte Ltd, 2002) at 160-161.

97. Article 22, *the Chinese Patent Law.*

98. Article 26, *the Chinese Patent Law.*

A comparison with Articles 52 and 53 of the European Patent Convention ("EPC") reveals substantial similarities between them. First, Article 25 (1) of the Chinese Patent Law excludes 'scientific discoveries' from patent protection; Article 52 (2) (a), EPC, similarly precludes 'discoveries, scientific theories and mathematical methods' from the scope of patentable subject matter.

Second, Article 25 (3) of the Chinese Patent Law explicitly excludes "methods for the diagnosis or for the treatment of diseases" from patentability while Article 52 (4), EPC assumes "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body" as incapable of industrial application and therefore not patentable. This is in sharp contrast to the practice in the United States where the patents for methods of surgery, therapy and diagnosis practiced on the human or animal bodies are "generally allowed."[99]

Third, both Article 25 (4) of the Chinese Patent Law and Article 53, EPC exclude "animal and plant varieties" from the scope of patent protection.

Concerning the patentability of genes, the relevant article is Article 25 (1), which excludes from patentability scientific discoveries as such, and accordingly, a material which is merely discovered in its natural existence cannot be patented. As a result, a gene or its DNA fragment which is found in nature existing in its natural state is regarded as a mere discovery and excluded from protection.[100]

However, a gene or DNA fragment becomes patentable along with the process to obtain it, if it is "isolated or extracted," for the first time, from its natural state, "definitively characterized" and has

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

100. See the official website of the State Intellectual Property Office of China, *available at* http://www.sipo.gov.cn/sipo_English/gftx_e/zyhd_e/t20031225_22943.htm. By November of 2001, "the protection of bio-tech and Internet-related innovations remains a grey area in China." At the time, "China still has no standards and particular requirements for applying for and certificating" the discoveries in the fields of DNA sequencing and genetically modified crops, see Xikai Wen, a senior research fellow with the State Intellectual Property Office, as quoted in *Patenting to Protect More New Techniques*, CHINA DAILY, April 11, 2001, *available at* http://www.china.org.cn/english/2001/Apr/10858.htm. But policy determined that the patentability of genes and biotechnology inventions are inevitable especially with regard to China's striving to develop its science and technology and more importantly, to its bid for membership in the WTO. *See* Wen, quoted *id.*, "Without a sound legal environment and incentives for the protection of intellectual property rights, China's dream of becoming a knowledge-based economy will not be realized," and Zhang Hanlin, executive director of the World Trade Organization Research Centre under the University of International Business and Economics of China, "Bringing DNA and gene modification technologies under the umbrella of intellectual property is of the utmost importance to China as they will become the major force behind China's agricultural modernization," as quoted, *id.*

a value of industrial application.[101] This practice is identical to that in Europe and the United States. Also, as in Europe and the United States, these genetic materials are treated as chemical substances in China.[102]

As already discussed, China is endowed with rich genetic resources, which may underscore the readiness of the government to extend patent protections to genes and other genetic inventions. It is reported that the Shanghai United Gene Technology Group alone has applied for 3,700 patents for genes dealing with cancer, obesity, high blood pressure and senile dementia.[103]

In respect to the patentability of transgenic animals and plants, the Examination Guidelines of the Chinese State Intellectual Property Office ("the Guidelines") broadly interpret animals and plants as falling into the scope of "animal and plant varieties" as specified in Article 25 (4) of the Chinese Patent Law.[104] Article 25 (4) disallows animal and plant varieties for patent protection. As is the case with the practice of the Chinese State Intellectual Property Office ("SIPO"), cells of plants and animals have been patented but no patents have ever been issued for the organs of plants and animals or plants and animals per se, transgenic or not.

By contrast, the United States grants patents to transgenic animals and plants. Considering the importance of the biotechnology industry and the encouraging effect of patents on development in that area, some recommended that the exception be deleted from the Chinese Patent Law and that in its stead, patent protection be granted to transgenic plants and animals.[105] However, such a recommendation is not commendable: as will be seen in the case of Monsanto's patent claims, allowing such patents may baffle farmers' practice and cause food shortages, amongst other drawbacks. It should be noted that micro-organisms are patentable in China as the SIPO construed micro-organisms neither as plants or animals nor as their varieties.[106]

The broad interpretation laid down in the Guidelines of animals and plants as "animal and plant varieties" means that plants can

101. Part 2, Ch. 10, Sec. 2 of the 2001 Examination Guidelines of the State Intellectual Property Office of China (SIPO) (hereinafter *the Guidelines*)

102. Xiaodu Zhang, *The Patentability of Biotechnological Inventions and Practices in China*, BIO-SCIENCE LAW REVIEW, August 10, 2001, *available at* http://pharma-licensing.com/features/disp/997365145_3b72959963a57. See also Lui, *supra* note 99, at 83, where it was stated that "Genetic materials are considered chemical substances. Thus genes, DNA, RNA, and chromosomes are patentable like any other chemical substances."

103. *China's Largest Gene Company Gets 3,700 Patents*, THE PEOPLE'S DAILY, June 26, 2001, *available at* http://fpeng.peopledaily.com.cn/200105/30/eng20010530_71375.html.

104. *See* http://www.sipo.gov.cn/sipo_English/gftx_e/zyhd_e/t20031225_22943.htm.

105. *See* Zhang, *supra* note 102.

106. Part 2, Ch. 10, sec. 7.1.2.1., *the Guidelines*.

only be protected under the Regulations for the Protection of New Varieties of Plants,[107] a *sui generis* system executing the International Union for the Protection of New Varieties of Plants ("UPOV"), of which China has been a member. There does not seem to be any legal regime to protect animals and animal varieties in China.

Article 25 does not preclude the processes used for producing animal and plant varieties and thus the processes, including genetic engineering processes, remain patentable if the claimed processes are "essentially non biological," a term which though seemingly self-contradictory, essentially requires that "the hand of man" has played a part in the success of the processes as established in the US Supreme Court case, *Diamond v. Charkrabarty*.[108] One question that remains is whether products obtained from such patented processes are patentable.

When the patent law was first amended in 1992, protection of a process patent was extended to the product directly obtained by the patented process.[109] But, there was a lack of court decision on the issue of whether an animal or plant directly derived from a patented process can be patented. Given the actual practice of the SIPO that no patents have so far been granted to animals or plants, it may be reasonable to assume that an animal or plant thus obtained cannot be directly protected by a patent. Further, from the official announcements that, "The protection of transgenic animal and plant could only be reached indirectly via the effects of the process patents,"[110] we may further confirm that transgenic animals or plants, howsoever obtained, cannot be patented in China.

Article 25(3) of the Chinese Patent Law conforms to Article 27.3(a) of the TRIPS Agreement. The excluded method of diagnosis such as endoscopic and ultrasonic methods refers to, "the process of discerning, studying and determining sickness within the human body or animal body."[111] The excluded method of treatment such as acupuncture, radiotherapy and immunization is defined as "the process of blocking, relieving or eliminating the illness of living human being or animals for the purpose of restoring health or relieving pain."[112] Furthermore, the Article 25 (3) exclusion also includes, "prophylactic treatment methods of diseases, methods of treating wounds, methods of contraception, artificial insemination, and embryo transfer."[113]

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107. *See* Lui, *supra* note 99, at 83.

108. (1980) 447 U. S. 303. *See* Emma Johnson, *A Benchside Guide to Patents and Patenting*, 14 NATURE BIOTECHNOLOGY 288, 290 (1996).

109. *See* Zhang, *supra* note 102.

110. *See* the SIPO's website: http://www.sipo.gov.cn/sipo_English.

111. Part 2, Ch. 2, sec.3.3.3.1, *the Guidelines*.

112. Part 2, Ch. 2, sec.3.3.3.2., *the Guidelines*.

113. *See* Lui, *supra* note 99, at 83.

However, methods not directly applied on the body can be patented, an example being "methods of treatment and diagnosis applied to tissue and other biological materials isolated and separated from the body."[114] As in conformity with the practice in Europe, compounds and products used for the treatment and diagnosis of diseases are patentable subject matter.

The grounds for the Article 25(3) exclusion in the Chinese Patent Law may be the same as those in Europe: humanitarian consideration and public morality necessitate it. As Professor Cornish pointed out, "the spectre of a single doctor reserving the performance of the most satisfactory, possibly life-saving, operation to his or her own team and extracting therefrom monopoly profits on the scale of a successful pop star seemed to put the matter beyond argument."[115] Furthermore, the assumption in the EPC of such methods as applied to human or animal body (not industrial!) as incapable for industrial application appears to be readily accepted in China.[116]

Besides the above exceptions from patentability, an invention, the exploitation of which is contrary to social morality or detrimental to public interest, shall not be patented.[117] The SIPO furnishes several examples which are regarded as contrary to social morality or detrimental to public interest:

(1) processes for cloning human beings and human beings being cloned;
(2) processes for modifying the germ line genetic identity of human beings;
(3) uses of human embryos for industrial or commercial purposes;
(4) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to human or animal, and also animals resulting from such processes.[118]

China is inclined to follow the European approach; almost identical examples can be found in the European Directive on the Legal Protection of Biotechnological Inventions ("the Biotech Directive").[119] In the case of reproductive cloning of the human being, the Chinese

114. *Id.* at 83.
115. CORNISH & LLEWELYN, *infra* note 258, at 255.
116. Part 2, Ch. 1, s 3.3, *the Guidelines.*
117. Article 5, *the Chinese Patent Law.* The same Article also provides that an invention contrary to the laws of the States cannot be patented either. Its meaning is further elaborated in Rule 9 of the Implementing Regulations of the 2000 Chinese Patent Law (hereinafter *the Implementing Regulations*): such an excluded invention shall not include the invention merely because its exploitation is prohibited by the laws of the State.
118. *See* http://www.sipo.gov.cn/sipo_English/gftx_e/zyhd_e/t20031225_22943.htm.
119. *i.e.,* Directive 98/144/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnology Inventions, 1998 O. J. (L213) 13.

government has recognized that it "will give rise to serious ethical, social, religious and legal problems" if abused and China's clear-cut stance toward opposing the cloning of human beings stems from the understanding that "it will pose great threat to the dignity of mankind."[120] Chinese scientists have also expressed their concerns over legal and ethical issues associated with the cloning technology and there is consensus that human cloning should be banned and that legislation is needed to regulate research in this area.[121]

Embryo stem cell research for the treatment and prevention of disease is regarded as beneficial and allowed in China but will be conducted under effective monitoring.[122]

B. Novelty

Novelty is defined in Article 22 of the Chinese Patent Law. According to the definition, novelty requires that no public disclosure of identical invention in publications in China or abroad can occur before the filing date. The prior art is any publicly available printed document in China or in any other countries. Public use and disclosure by other means *in China* before the filing date would destroy novelty. Prior public use refers to manufacturing, selling, importing or modeling the invention within China; disclosure by other means refers to disclosure by communication in conference, oral reporting and broadcasting through radio or television and so on.[123] An application by any other person for the identical invention, if published by the SIPO before the above filing date, would also destroy novelty.

Novelty of an invention can still be maintained if, within six months before the date of filing, it was first exhibited at an international exhibition sponsored or recognized by the Chinese government, or first made public at a prescribed academic or technological meeting, or disclosed without the consent of the applicant.[124]

Now in China, so far, neither has the Re-examination Board or the court decided on the issue of novelty concerning gene-related inventions, nor do the Guidelines of the SIPO contain any relevant provisions.[125] But the Guidelines include some provisions in respect to

120. Statement by Mr. Chen Xu, the Representative of the People's Republic of China at *the Ad Hoc Committee on the Convention Against the Reproductive Cloning of Human Beings, available at* http://www.china-un.org/eng/zghlhg/flsw/t28563.htm.

121. *Chinese Government, Scientists Oppose Human Cloning*, THE PEOPLE'S DAILY, November 30, 2001, *available at* http://english.peopledaily.com.cn/200111/30/eng20011130_85687.shtml.

122. *Id.* China has successfully regenerated and duplicated gastrointestinal organs by culturing stem cells. See *China Succeeds in Duplicating Organ From Stem Cell*, XINHUA NEWS AGENCY, November 19, 2001, *available at* http://www.china.org.cn/english/material/22357.htm.

123. Part 2, Ch. 3, sec.2, *the Guidelines.*

124. Article 24, *the Chinese Patent Law.*

125. *See* Zhang, *supra* note 102.

chemicals which may be relevant to biotechnology inventions. Therein, it is stipulated that if prior art contains sufficient information to enable a skilled worker to repeatedly obtain the same claimed compounds or products, novelty is destroyed, whereas novelty is maintained if no information in the prior art can enable execution of the claimed subject matter.[126]

C. *Inventiveness*

To satisfy the requirement of inventiveness, the invention must have "prominent substantive features" and represent "a notable progress" through the comparison of the claimed invention with the technology existing before the date of filing.[127] The Guidelines of the SIPO have laid down detailed approaches toward the issue of inventiveness. According to the Guidelines, apart from the above primary approach, secondary indicia of inventiveness may also be taken into account, which are "well-known tests such as providing a solution to a long-felt problem, overcoming technical prejudice, unexpected results, and commercial success."[128]

In respect of chemicals, if a claimed chemical compound has a similar structure to any known compound, then it must be demonstrated that the claimed compound has the unexpected use or effect. However, if its structure is different from that of any known compound, then no such demonstration is necessary in order to fulfill the requirement of inventiveness.[129] As genes are treated as chemicals, such a test is likewise applicable to the inventiveness test for claimed genes.

D. *Practical Application*

Practical application is defined as meaning that "the invention or utility model can be made or used and can produce effective results."[130] In Europe, "industrial application" is instead employed and described as follows; "an invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture."[131] The industrial element does not seem to be pressed in China. For example, if a product invention can be manufactured in laboratory, not necessarily industrialized, it can qualify as capable of practical application.

In the United States, surrounding the patentability of business method, the test of practical application was favorably adopted by a

126. Part 2, Ch. 10, Sec. 5.1 & 5.2, *the Guidelines.*
127. Article 22, *the Chinese Patent Law.*
128. *See* Lui, *supra* note 99, at 84.
129. Part 2, Ch. 10, sec. 5.5, *the Guidelines.*
130. Article 22, *the Chinese Patent Law.*
131. Article 57, *the EPC.*

federal court which held that the test is satisfied so long as a "useful, concrete and tangible result" is produced.[132] Likewise, Stephen Kunin, the Deputy Commissioner for the United States Patent Examination Policy, believed that searching for a practical application is another way of determining if the claimed invention has a specific and substantial utility. He outlined the identification of "any significant functionality which achieves concrete, useful and tangible results" as the United States Patent and Trademark Office's ("USPTO") preferred methodology for determining if the practical application test is satisfied.[133]

The American approach is rather lax without any requirement of technical effects. In China, concerning the patentability of business method, an official announcement placed emphasis on the technical factors: the method as such is excluded by Article 25 but will constitute a patentable subject matter if it "adopts technical means, resolves a technical problem and creates a technical effect."[134] However, it is unknown to what extent such a technical effect is pressed when it comes to the test of practical application in the general sense.

It is still unknown whether practical applicability in China is synonymous with industrial applicability or with the American usage of the same terminology.

E. Enabling Disclosure

Article 26 requires the inventor to describe his invention in the written description "in a manner sufficiently clear and complete so as to enable a person skilled in the relevant field of technology to carry out" the invention. It is noteworthy that the applicant must disclose in detail "*the optimally selected mode* contemplated" by him/her for carrying out the invention.[135]

For an invention relating to a DNA fragment, gene, peptide or protein, relevant experimental evidence may need to be provided. Where the claimed invention offers a technical solution which can only be proved by the result of the experiment, failure to provide the experimental evidence shall entitle the SIPO to deem the invention to be non-enabling.[136]

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132. State Street Bank & Trust Co. v. Signature Financial Group Inc., 149 F.3d 1368, 1373 (Fed. Cir. 1998). The *State Street* approach was followed in AT&T Corp Excel Communications Inc., 172 F3d 1352 (Fed. Cir. 1999).

133. Robert V. Donahoe, *PTO Speaks on Business Method Patents at ABA Conference*, 2000 B. C. INTELL. PROP. & TECH F. 072100, *available at* http://www.bc.edu/bc_org/avp/law/st_org/iptf/headlines/content/2000072101.html.

134. See the website of the SIPO: http://www.sipo.gov.cn.

135. Rule 18 (5), *the Implementing Regulations.*

136. *See* http://www.sipo.gov.cn/sipo_English/gftx_e/zyhde/t20+-031225_22943.htm.

If the technical solution of the invention is to diagnose or treat diseases, the qualitative or quantitative data of the laboratory test (including animal test), or clinical test, shall be provided sufficiently to enable the person skilled in the art to prove that the technical solution of the invention may achieve the expected purpose or effect. The effective amount, method of use or preparation etc. shall be disclosed sufficiently to enable the person skilled in the art to carry out the invention.[137] The above benchmark must be followed in order to satisfy the requirement of enabling disclosure for genes and related inventions. Some of the data may be submitted after the filing date, but such submission is not allowed to be added to the specification or used to extend the scope of a claim.[138]

Where the claimed invention concerns a biological material which is not publicly available and which cannot be described in the specification so as to satisfy the enabling disclosure requirement, a specimen of the material shall be deposited with a recognized depository institution on or before the date of filing.[139] In addition, the applicant is also required to submit at the time of filing or within four months from the filing date at the latest, a receipt of deposit and the viability proof from the depository institution.[140] As China has acceded to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, any international depository institution constituted under the Treaty is recognized by the SIPO.

Since the publication of the patent application, any entity or individual can now request a sample of the deposited biological material.[141] The request should be made to the Patent Administration Department under the State Council and the entity or individual making the request must undertake not to make the biological material available to any other person, and shall "use the biological material for experimental purpose only before the grant of the patent right."[142] In comparison with the European Biotech Directive, there

137. *Id.*
138. Lui, *supra* note 99, at 84.
139. Rule 25 (1), *the Implementing Regulations.*
140. *Id.*
141. Contrast the practice in Europe: art. 13.2 of the Biotech Directive provides that "Access to the deposited biological material shall be provided through the supply of a sample: (a) up to the first publication of the patent application, only to those persons who are authorised under national patent law; (b) between the first publication of the application and the granting of the patent, to anyone requesting it or, if the applicant so requests, only to an independent expert; (c) after the patent has been granted, and notwithstanding revocation or cancellation of the patent, to anyone requesting it."
142. Rule 26, *the Implementing Regulations*. Herein, "only" qualifies "experimental use." This is clear from the Chinese version of *the Implementing Regulations*. As expected, in the case of discrepancy or ambiguity, the original text in Chinese prevails. See the SIPO's website, *available at* http://www.sipo.gov.cn/sipo_English/flfg_e/zlflfg_e/t20020327_4703.htm.

are some uncertainties in the above requirements. It requires the requester to use the biological material for experimental purpose only before the grant of the patent, but fails to provide information as to whether the requester can use such material for other purposes after the grant.[143] The emphasis on "before the grant of the patent right" seems to indicate that the restriction to the experimental use should not apply after the grant.

In respect to the requirement for disclosure of "the optimally selected mode contemplated," it may have been incorporated in the Chinese Patent Law to comply with the TRIPS Agreement; Article 29 of the Agreement provides that a member state, "*may* require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date (emphasis added)." The "best mode" requirement is very unique to the United States patent law in the sense that there is no such requirement in the European Union patent legislation or Japanese patent law. It is not compulsory under the TRIPS Agreement; it is not quite clear why China has followed the American rather than the European practice. In the United States, as explained by Judge Rich in *In re Gray*, "Manifestly, the sole purpose of [the best mode requirement] is to restrain inventors from applying for patents while at the same time concealing from the public preferred embodiments of their inventions which they have in fact conceived."[144] Maybe the incorporation of the requirement in the Chinese Patent Law was intended to achieve the same.

In meeting the requirement under the Chinese patent law, the American situation may have some persuasive authority. Section 112 of the 1952 U.S. Patent Act requires a patent applicant to disclose his/her invention in a written description specifying "the manner and process of making and using [the invention]," "in such full, clear, concise, and exact terms as to *enable* any person skilled in the art. . .to make and use the [invention]," and to disclose "the *best mode contemplated*. . .of carrying out his invention (emphases added)."[145] Though the "best mode" requirement and enabling requirement are collapsed into the same section, they are, in fact, distinct and separate from each other; in other words, "even if the disclosure of the patent application is fully 'enabling,'" the best mode requirement must also be met.[146] Unlike the enabling requirement which is objec-

143. Compare art. 13.3 of the Biotech Directive which provides that "The sample shall be supplied only if the person requesting it undertakes, for the term during which the patent is in force: (a) not to make it or any material derived from it available to third parties; and (b) not to use it or any material derived from it except for experimental purposes, unless the applicant for or proprietor of the patent, as applicable, expressly waives such an undertaking."

144. *In re* Gray, 309 F.2d 769, 772 (C.C.P.A. 1962).

145. 35 U. S. C. §112 (1975).

146. HAROLD C. WEGNER, PATENT LAW IN BIOTECHNOLOGY, CHEMICALS & PHARMACEUTICALS 794 (2d ed. 1994).

tive, the best mode contemplated is entirely the subjective best way of carrying out the invention appreciated by the inventor as at the filing date.[147] In *DeGeorge v. Bernier*, it was stated that, "there is no objective standard by which to judge the adequacy of a best mode disclosure. . .only evidence of 'concealment'. . .whether accidental or intentional, is considered."[148] In the case where there is a better method or mode but the patentee failed to disclose it, not because he tried to conceal it, but rather because he did not know it or he did not appreciate that it is the best method, then it cannot be held that the best mode requirement is not fulfilled.[149]

CONCEPTION OF INTELLECTUAL PROPERTY RIGHTS IN CHINA

The patent is said to promote the development of society by securing the incentive through the exclusive rights for inventors and innovators; but it may tax society and paradoxically, hinder the development of the very industry it seeks to promote, which is well illustrated by the case of the "tragedy of the anticommons" as exemplified at the beginning of the essay. The perennial quest is to determine where the exclusive rights should end and legitimate public use should be allowed. In the West, unsurprisingly, with the patenting of biotech inventions, the issue has been pushed to the center of contention and concerns expressed over the monopolistic right and its inhibitive effects on the science community and indeed, society at large.

In response, it has been proposed that the experimental use exception and compulsory licensing should solve or at least mitigate the adverse effects of patents on the development of biotechnology. As observed by Professor Merges, basically, the experimental use exception means that, "a patentee will not be allowed to prevent experimentation using a patented product or process for bona fide research activities designed to further scientific knowledge."[150] Some believed the purpose of the research, be it commercial or non-commercial, to be irrelevant, the rationale being that "the benefit to society of the follow-on research does not depend on whether the research is done for commercial or non-commercial purposes."[151] The compulsory li-

147. *Id. See also* PAUL GOLDSTEIN, COPYRIGHT, PATENT, TRADEMARK AND RELATED STATE DOCTRINES 387 (3d ed. 1993) where it is likewise said that "The enablement requirement is objective; the best mode requirement is subjective."

148. 768 F.2d 1318, 1324 (Fed. Cir. 1985).

149. Benger Laboratories Ltd v. R. K. Laros Co., 209 F. Supp. 639, 644 (Ed Pa. 1962).

150. Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1073 (1988).

151. *See* John Barton, *Patent Breadth and Antitrust: A Rethinking*, November 27, 1995, *available at* http://www.ftc.gov/global/barton.htm.

cense is "a statutory mandate that the [patent] rights must be licensed to all comers willing to pay the pre-set price."[152]

Now what is of interest is whether the same sort of contention and concerns are shared in China and whether the two proposals are applicable there. In the ensuing discussion, the understanding of intellectual property rights ("IPRs") in China is visited to see whether there are well-balanced views on the issue there; particularly whether the inhibitive effects are given enough credence. Having found the lack of the downside of the patent addressed there, several case studies are conducted to show whether the said effects are prominent and well felt. Based on the affirmative outcome of the case studies, then, the status quo in respect to the experimental use exception and compulsory licensing in the Chinese Patent Law is critically examined.

An extensive, if not exhaustive, research effort into the literature available in China reveals that there is a dearth of literature opposing the implementation of a strong patent system. In a general sense, a strong patent system is viewed by the developed countries, though by no means shared with the developing countries, as "a necessary prerequisite for investment in research and development and an engine for driving technology transfer."[153] Such a view, however, seems readily accepted by the Chinese government and the patent is regarded as "the rules of the game by which the other players compete."[154] As the former Chinese President Jiang Zemin pointed out, a patent system of international standard is crucial to the long-term development of China's economy.[155]

The then Vice Premier and now Premier Wen Jiabao approvingly emphasized the important role of an intellectual property system for the following reasons:

(1) The IPR system was needed for establishing a socialist market economy, and was conducive to setting up a favorable market order and a market operation mechanism;

(2) It was needed for achieving scientific progress and technological innovation, and was favorable to protecting inventions-creations, and to encouraging the creativity of technicians and researchers;

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152. Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations,* 84 CAL. L. REV. 1293, 1295 (1996).

153. Jorg Reinbothe & Anthony Howard, *The State of Play in the Negotiations on TRIPs (GATT/Uruguay Round)*, 5 EIPR 157, 162 (1991).

154. William E. Beaumont, *The New Patent Law of the People's Republic of China (PRC): Evidence of a Second Chinese 'Renaissance,'* 27 IDEA 39, 39 (1986).

155. White Paper on the Intellectual Property Rights Protection in China in 2000, *available at* http://www.sipo.gov.cn/sipo_English/gftx_e/zscqbhbps_e/t20020306_4317.htm.

(3) It was needed for building a socialist country ruled by law, and could help the construction of a sound legal system;
(4) It was needed for carrying out the reform and opening up policy, and was conducive to expanding international exchange and cooperation;
(5) It was needed for the construction of spiritual civilization, and was favorable to creating a social environment where knowledge, intellectuals and talents were respected.[156]

The predominance of this one-sided stance toward IPRs may well be a silhouette of the permeation of politics in Chinese legislation. But considering the substantial relaxation of academics from political domination, it is puzzling that opposition to this ever-strengthening monopolistic right of patent was minimal even in academic circles. Maybe the Chinese intellectuals, long being cast in the category of "second-rate citizens," are now unanimously determined not to make further sacrifices for their knowledge without concrete and material rewards. Of course, we may rightly assume that the industrial sector was not so much educated on the issue as the academics to offer any sound opposition at the early stage of the patent law.

Indeed, in modern China, the social pendulum has swung quite to the opposite from an era when patent rights were dismissed as capitalist and intellectuals were exiled to the countryside to be "re-educated" by farmers. This is definitely encouraging and undoubtedly will facilitate the country's striving for the advancement of science and technology and economic prosperity. However, the patent is capable of exerting mischief and may inhibit the achievement of those very goals if not properly controlled. Whereas its mischievous effects may or may not be obvious at its present infantile stage in China, it in no way indicates that China should not think carefully or rethink the extent of this monopolistic right and its long-term effect. In fact, the adverse effect of this exclusion right has begun to show up in China, as is illustrated in the following cases.

Case 1: Monsanto's Claims

Transnational agro-chemical giant Monsanto filed a worldwide patent application (W0/0018963) on April 6, 2000 in up to 101 countries, including China, Europe and the United States, claiming a total of 64 exclusive rights for genetically engineered soybean varieties and seeds.[157] Monsanto identified a molecular marker ("QTL") by screening and comparing some domesticated and wild soy varieties.

156. White Paper on the Intellectual Property Rights Protection in China in 1999, *id.*

157. Wang Yuanyuan, *Monsanto Under Fire For 'Pirating' Chinese Soy Strain,* CHINA DAILY, October 30, 2001, *available at* http://www1.chinadaily.com.cn/bw/2001-10-30/41353.html.

QTL will then be used to help identify high-yielding plants. The specific wild soya was originated from South China and Monsanto claimed a natural gene sequence thereof.[158] The claimed patent protection would apply to "all plants [wild and domesticated] in which these markers occur as well as the screening processes to identify the markers, and any breeding method which uses them - whether for soya bean or any other crop."[159]

This patent application had an interesting prelude. Back in 1994, the EPO approved Agracetus (then-subsidiary of W.R. Grace & Co.), a US-based biotech company, "an exceptionally broad 'species patent,'" a European Patent No. 301,749, granting "exclusive monopoly over all forms of genetically engineered soybean varieties and seeds - irrespective of the genes used or the transformation technique employed."[160] Even Monsanto's lawyers wrote that the soybean patent should be "revoked in its entirety," that it is "not. . . novel," "lacks an inventive step," and further noted that "sufficient disclosure [of scientific method] is woefully lacking."[161] With the acquisition of Agracetus by Monsanto in 1996, the latter withdrew its challenge, announcing that it would defend its newly-acquired patent.[162]

Greenpeace dubbed Monsanto a "bio-pirate," accusing it of getting germplasm from China through illegal means.[163] Greenpeace further warned of the potential adverse effects if the patent application were to be approved. First, it would considerably put limitation on research, breeding and the use of soya with the claimed markers, thereby impeding scientific development and endangering food security as a result of restrictions on breeding. Soybeans originate in China and the country is home to more than 6,000 wild soya varieties, over 90 percent of the global total.[164] Soybeans are an important vegetable and protein crop in China and many other Asian countries and thus the effect of the potential patent on food security and research is vast.

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158. *Id.*

159. John Gittings, *China Faces Agricultural Revolution*, THE GUARDIAN, November 13, 2001, *available at* http://www.guardian.co.uk/Archive/Article/0,4273,4298323,00.html.

160. ETC Group, *Patently Wrong! Monsanto Species Patent on Soy Beans Upheld in Munich*, June 5, 2003, *available at* http://www.ratical.org/co-globalize/patentlyWrng.txt.

161. ETC Group, *Monsanto Monopoly Patent under Scrutiny*, April 28, 2003, *available at* http://www.etcgroup.org.

162. *Id.* In the United States, the species-wide cotton patent, and broad claims on all GM soybeans are not allowed.

163. The specific wild soya in the patent application was described as originating from South China, but Monsanto said that it obtained the germplasm from the U.S. National germ-plasma collection. See *id.*

164. Greenpeace, *Monsanto's Biopiracy of the Soybean*, October 22, 2001, *available at* http://archive.greenpeace.org/geneng/reports/gmo/ChinaSOY22oct.pdf (hereinafter *Monsanto's Biopiracy*).

Second, the farmers who grow soya with the markers would suffer as they would be prohibited from exchanging seeds with other farmers. In addition, if they grow it unknowingly or conduct their own breeding, they would infringe and risk the danger of being sued by Monsanto. As the patent covers both wild and domesticated soya, those "farmers who have been growing high-yielding soybean varieties which happen to contain the molecular markers in question, would be obliged to pay royalties to Monsanto for each harvest."[165]

Third, even if this patent may not be approved by the Chinese government, importing Chinese soya with the markers to countries where the patent is applicable would infringe.[166]

Despite years of battle by civil society and industry to have the patent revoked, the patent was upheld by the EPO on May 6, 2003. Huge opposition ensued. Jim Thomas, of the Canada-based ETC Group's Oxford office, argued that, "It's a bit like publishing a badly written cake recipe and then claiming ownership of any cakes baked by anybody using any recipe anytime in the future. . .Monsanto now controls 100% of the world's genetically engineered soybeans covering 36.5 million hectares in 2002 - that's over half of the world's total soybean area."[167]

In China, Xue Dayuan, senior researcher of Nanjing Institute of Environmental Sciences under the State Environmental Protestation Administration of China, called Monsanto's patent claim "genetic colonialism" that exploits and controls genetic resources from developing countries rich in biodiversity,[168] "without the prior informed consent of the government or the community where the materials originated from."[169] Professor Junyi Gai of Nanjing Agriculture University believed that markers existed in nature and that Monsanto did not identify the gene directly related to high-yield, nor did it separate or clone such a gene, and hence Monsanto's claim is not an invention but a mere discovery and cannot be patented. High-yielding soya bean wild varieties have been bred by generations of farmers and each year they select the best seeds to be planted for the next season, which is "an accumulation of peasant (sic) experience."[170]

Now with China's WTO membership granted, it is uncertain how the problem can be resolved. "However this problem is resolved, it illustrates the growing impact of the global agribusiness on Chinese farmers who can do little but yield to market mechanisms."[171]

165. *Id.*
166. *Id.*
167. *Id.*
168. *See* Wang Yuanyuan, *supra* note 157.
169. *Monsanto's Biopiracy*, *supra* note 164.
170. *See* Gittings, *supra* note 159.
171. *Id.*

China has been striving to eliminate starvation and obviously biotechnology is taken as the light at the other end of the tunnel. However, as demonstrated in this case, a patent is capable of baffling the very purpose it is supposed to serve. Thus, its inhibitive effect on research and indeed on the broader goal of the society should be kept within sight by the Chinese government amongst all its endeavors to keep up with the international standards of the patent system.

Case 2: Biochip

A biochip refers to an array of biochemically-active substances arranged on a plastic, glass, or silicon substrate.[172] As the biochemicals can include DNA, genes, antibodies or proteins, biochips can take on many pseudonyms such as microarrays, gene chips, or DNA chips depending on which are deposited on the substrate. For example, in a DNA chip, oligonucleotides complementary to known genes or expressed sequence tag are deposited on a miniature matrix by engineering process.[173]

The deposited biochemicals in a biochip can produce an easily measurable effect when they react with specific substances such as a virus antigen. The effect usually includes fluorescence or electrochemical responses, which can be measured by the detection system, processing system and memory integrated into the substrate. As a result, the detection of substances washed over the chip is "quick, repeatable and automatic."[174] The decoding of SARS virus gene sequence was completed in a matter of months in comparison with the years spent on decoding the influenza virus or the smallpox virus.[175]

As a rapid and accurate method of screening biochemicals, the biochip is widely accepted by pharmaceutical companies to increase turnaround time for new drugs and improve drugs already developed. The biochip can also be applied in forensic science to allow suspects or evidence to be DNA identified in a matter of seconds.

Unsurprisingly, with a view to the benefits, the development of the biochip has been undertaken by many countries. In China, some dozen biochip companies have been the major force in vigorously pushing biochip research into commercial products. Most of the companies are derived from or associated with research institutes or universities with biochip expertise and related technologies. For

172. Ed White & Thomson Derwent, *The Rise and Rise of Bicohip Patenting—An Engineering Perspective, available at* http://thomsonderwent.com/media/miscpdfs/biochip_pat.pdf.

173. *DNA Chip (microarray), available at* http://www.unc.edu/~zhangz/topics/#03.

174. *See* White & Derwent, *supra* note 172.

175. *Id.* So far three separate applications for the genetic sequencing of the SARS virus have been submitted the US PTO by the federal government, the British Columbia Cancer Agency and the University of Hong Kong through its agency Versitech Ltd., See Barbara Carroll, *War Over SARS: Who Gets the Patent?* May 9, 2003, *available at* http://www.newsmax.com/archives/articles/2003/5/9/132657.shtm.

example, the United Gene Science & Technology Group backed by Fudan University in Shanghai started to mass-produce DNA chips in 2000, being the first in China to do so. By mid-2000, the company had obtained the patent rights for 2100 genes.[176] Another example is Chen Jing, who headed a $40 million, two-part national biochip initiative. One part is a nonprofit research center based on work at Tsinghua University and three other top medical schools and universities. The other is a for-profit company, Capital Biochip, which spun off an affiliate in Shenzhen—ChipScreen BioSciences—that will employ biochips to help isolate disease-fighting substances from traditional Chinese remedies and other natural products. Once isolated, such active ingredients can be developed as proprietary pharmaceuticals.[177]

A long list of other companies in China are also involved in the development of biochips: from Shaanxi Lifegen Company having successfully developed high-density DNA chips with excellent quality to BioStar Genechip Inc., Shanghai, which is engaged in the development of a series of cDNA arrays for gene expression studies, and to Shenzhen Yishengtang Biological Product Company undertaking the development of DNA chip products for medical diagnosis, such as for diagnosis of infection by hepatitis B virus ("HBV") and hepatitis C virus ("HCV"). In addition, the DNA chips for HBV and HCV infection diagnosis developed by Shaanxi Chaoqun Science & Technology Co., Ltd have now been approved by China's State Drug Administration ("SDA") for production and clinic use.[178] Indeed, "the sheer number of institutions and companies in China developing [biochips] means they are a big player as a nation."[179] The number of the patent applications for biochips worldwide has jumped from about 300 in 1992 to about 4000 in the year 2002. In 2002, China ranked second only to the United States, comprising 23% of the total 4000 or so applications.[180]

However, beneath the robust development, the problems and dilemmas facing the scientific community and commercial companies in the West concerning the biochip as addressed at the beginning of this essay may appear soon in China. China formally recognized the patentability of genes and genetic inventions in 2002. The infantile nature of a patent system and the limited number of patents granted for the area are seemingly out of pace with the scale of research and development of the biochip in China. This may well mean that the

176. *DNA Chips Put into Mass Production,* THE PEOPLE'S DAILY, July 13, 2002, *available at* http://fpeng.peopledaily.com.cn/200007/13/eng20000713_45400. html.

177. *See* Stipp, *supra* note 73.

178. Chao Chen and Ning Dan, *Advances in Biochip Research and Commercial Development in China, available at* http://www.863.org.cn/english/Forum/3.doc.

179. White & Derwent, *supra* note 172.

180. *Id.*

Chinese biochip industry, to a large extent, has been developed in disrespect of relevant patents granted in other countries and possibly in China as well.

With China's WTO membership and its increasingly important role and competitive powers in the biotechnology industry to be exhibited, not to mention the international sale of the biochip, the proprietors of the relevant patents will inevitably seek their shares of the big pie in China and worldwide. A patent owner is entitled to put an end to the unauthorized use of his/her patent, thereby hampering the further development of the product using the patent. In theory, this scenario is likely to occur in particular in biotechnology where there is no alternative means for the patented genes or sequences. In practice, this would not happen and commercial consideration would prevail.[181] However, with the likelihood of its occurrence, the bargaining leverage which the proprietors will bring to the negotiating table for their preferred amount of royalties is realistic. Besides, each patent owner may overestimate the contribution as made by his patent and demand disproportionate amount of royalties, thereby resulting in the product not being developed at all or leading to the collapse of the industry—indeed the "tragedy of the anticommons."

In fact, the inhibiting effects of patents on the development of the biochip have begun to emerge in China as noted by the SIPO.[182] According to the SIPO, the applications for patents for inventions relating to novel human genes and DNA chips will decline from the present level in the domestic application. On the one hand, there are technical problems in the finding of novel genes with identified functions. But "the reason that biochip patents have jumped from 300 to 4000 in a single decade is mainly due to this hunt for new and novel genes and proteins to go onto the chips. Putting different types of biochemicals onto the chips changes what the chip can do, what chemical it screens for and who will buy it."[183] On the other hand, the limited number of its own patents for novel genes will put China at "the risk of infringement of related genes after DNA chips are entered into market."[184] This would limit the investigation of DNA chips.

Another limiting factor lies in the "hardware" side of the DNA chips. Some warn that "China's biochip industry also needs to have

181. But in a patent dispute between Sony and BYD, a Chinese battery maker, Sony is not to ask for monetary damages but to prohibit the marketing acts of BYD. *See Sony to Sue Chinese Battery Maker BYD for Alleged Patent Infringement*, AGENCE FRANCE-PRESSE (via CLARINET), July 8, 2003, *available at* http://quickstart.clari.net/qs_se/webnews/wed/cj/Qjapan-chinatechnology.RPRI_Dl8.html (hereinafter *Sony to Sue Chinese Battery Maker*).

182. *Patent Application and Examination*, *available at* http://www.sipo.gov.cn/sipo_English/gftx_e/ndbg_e/2001nb_e/t20020426_5297.htm.

183. White & Derwent, *supra* note 172.

184. *Patent Application and Examination*, *supra* note 182.

systematic patent-protected key technologies in related fields,"[185] such as semiconductor fabrication techniques underlying the substrate. This may imply that the present situation of lack of systematic patent rights as owned by the Chinese biochip industry bodes ill for its future development.

In order to further demonstrate the possibility of the "tragedy of anticommons" occurring to the Chinese biochip industry, the following case examines, in parallel, the patent row in which the Chinese manufacturers of DVD players were embroiled. The Chinese DVD industry has been developed in disrespect of the relevant patents but now with the success of the industry established, the issue of patent infringement has to be dealt with.

Case 3: DVD

Following compact disks (CD-ROM) for computers and VHS tapes and laserdiscs in the entertainment industry, the joint development of a new high-density medium known as Digital Video Disk (DVD) was first announced by SONY and Philips in 1994.[186] In the following year, Sony was the first to showcase its DVD technology. Soon after, Time Warner and Toshiba held press conferences to announce their version of the DVD. Contentions began to build between the two formats. Following a report by Apple, Compaq, Fujitsu, HP, IBM, and Microsoft in which the software and hardware giants collectively refused to support the dueling standards, Sony, Philips, and Toshiba decided to unite in their efforts to create the DVD.[187] After the settlement of the relevant issues, such as the exchange and pooling of technologies and the split of royalties, DVD as an industry standard was announced in November 1995 and backed by major players in the CE, IT and movie industries. The first players appeared in Japan in November 1996, followed by U.S.-made players in March 1997.[188] Thus was born a whole new industry—the DVD industry.

In China, the DVD industry has experienced robust development, especially in recent years. By the year 2002, there were already more than 100 domestic DVD manufacturers producing about 30 million DVD players, almost doubling the 2001 figure. In 2001,

185. Chao Chen and Ning Dan, *supra* note 178.

186. Robert Chapin, *The History of DVD*, *available at* http://www.miqrogroove.com/writing/History%20of%20DVD.html.

187. *Id.*

188. Mary Bellis, *DVD*, *available at* http://inventors.about.com/library/inventors/bldvd.htm. The different terminologies used can be understood in the following light: "DVD-Video is the usual name for the DVD format designed for full-length movies and is a player that will work with your television set. DVD-ROM holds computer data and is read by a DVD-ROM drive hooked up to a computer, DVD-RAM is the writeable version. DVD-Audio is a player designed to replace your compact disc player." *Id.*

China exported 12 million DVD players with the overall trading volume of the DVD players in the world market estimated at just around 30 million.[189] That export figure jumped to 20 million players in 2002, accounting for up to 70 percent of the global DVD market.[190] Indeed, the Chinese DVD industry was making a big noise.

However, for a manufacturer to produce DVD players, it must obtain licenses for a range of patents, owned by a consortium of technology companies known as the 6C, namely Hitachi, JVC (Japan's Victor Co.), Toshiba, Matsushita, Mitsubishi, and Time Warner Inc.,[191] and owned by the 3C, i.e., Sony, Philips and Pioneer,[192] and possibly by others. In the case of the Chinese DVD manufacturers, the DVD players were manufactured without the proper licenses procured and royalties paid—-a perennial practice with the Chinese manufacturing industries.[193]

In November 2000, the 6C presented a plan to leaders of the China Audio Industry Association ("CAIA") in Beijing, requiring royalties from manufacturers of DVD discs and equipment. Terms were $4 per unit or 4% of the net selling price, whichever was higher, for each DVD player, and $1 per unit or 4% of the net selling price for each DVD decoder.[194] Similar steps were followed by the 3C requiring the paying of licensing fees ranging from 15 US cents to US $4 on the whole gamut of DVD products, from discs to players.[195] Furthermore, because the DVD format uses the MPEG-2 video standard, another separate royalty must be paid to MPEG LA, the MPEG licensing authority. Payments must also be made for Dolby sound[196] and to owners of various copy protection systems.[197] The heavy charges would obviously raise the price of the DVD player and curb domestic demand in China, now the world's second largest DVD market next to the United States, not to mention the backlash on the

189. Xing Bao, *Pending Sentence*, CHINA DAILY, April 18, 2002, *available at* http://app1.chinadaily.com.cn/star/2002/0418/bz10-1.html.

190. Benjamin Kang Lim, *China Eyes Its Own EVDs to Replace DVDs*, BEIJING (*Reuters*), November 18, 2002, *available at* http://in.tech.yahoo.com/031118/137/29j5z.html.

191. Barry Willis, *Chinese DVD Makers Facing Lawsuits*, March 24, 2002, *available at* http://www.guidetohometheater.com/news/11250/.

192. *See* EASTDAY.COM, October 11, 2001, *available at* http://www.china.org.cn/english/DO-e/20357.htm.

193. *See* Willis, *supra* note 191.

194. *Id.*

195. EASTDAY.COM, *supra* note 192.

196. *Dolby's Patent Pressures China's DVD Industry*, *available at* http://www.ccpitpatent.com.cn/news.htm.

197. Mike Clendenin and Junko Yoshida, *Taiwan Joins Chinese Effort on Proprietary DVD Format*, E.E. TIMES, May 24, 2002, *available at* http://www.eetimes.com/story/OEG20020524S0091.

export. What is more, "If the fee is collected, a large number of small and medium-sized DVD manufacturers will break down."[198]

Legal complexities ensued. First, it needed to be established whether Chinese patent authorities have approved the relevant patents in China.[199] For example, Phillips' patent application, which was submitted five years ago, has still not been approved.[200] Second, it needed to be confirmed whether domestic DVD producers have used the technologies if patented in China.[201] Third, if the patent fee is justifiable, then the problem is just how much Chinese companies should pay.[202] In an open letter, the Chinese manufacturers also expressed concerns over the possibility of anti-competition being exercised by the 3C and 6C in their cross-licensing agreement.[203] The letter said:

> 6C and 3C claimed that they have a so-called "cross licensing" between each other. But they have always refused to publicize the content of this "cross licensing". It is dubious whether they are paying patent fees to each other or how much is paid. Many of the benefit group members are both component suppliers and DVD player manufacturers. If there is a special rate between each other, that will constitute an unfair competition. Chinese DVD player suppliers will be in an inferior position to compete with their opponents of the benefit group members.[204]

Whilst the disputes continued, both the 6C and 3C were prepared to stop imports of unlicensed DVD players and to bring lawsuits against companies that shipped them.[205] In February 2002, the European Union held shipments of 10,000 Chinese-made DVD players due to royalty nonpayment at the urging of the 3C group.[206] In

198. Shan Gensheng of Jinzheng Company, a major Chinese DVD manufacturer. *See DVD Patent Problem to be Solved Within One Year*, CHINA DAILY, October 9, 2001, *available at* http://www.china.org.cn/english/investment/20234.htm (hereinafter *DVD Patent Problem*).

199. Professor Liu Chuntian of Renmin University of China, quoted, *id.*

200. *Id.*

201. EASTDAY.COM, *supra* note 192.

202. See *DVD Patent Problem*, *supra* note 198.

203. Traditionally, the US antitrust law had been hostile to patent pools; for example, in 1975, a consent decree dismantled the aircraft patent pool, posing treble damages and an injunction. *See* Heller & Eisenberg, *supra* note 10, at 700. But the past decade has witnessed the increased use of patent pools and the US Department of Justice has sanctioned the MPEG patent pools and the DVD-ROM and DVD-video formats patent pools. *See* Michael A. Carrier, *Resolving the Patent-Antitrust Paradox Through Tripartite Innovation*, 56 VAND. L. REV. 1047, 1094 (2003).

204. *Royalties of DVD Players-China Manufacturers Answer*, February 20, 2002, *available at* http://www.dvd.reviewer.co.uk/news/article.asp?Index=5493 (hereinafter *Royalties of DVD Players*).

205. *Id.*

206. *Id.* See also *China in DVD Royalty Row*, March 7, 2002, *available at* http://news.bbc.co.uk/1/hi/business/1860621.stm where the Chinese officials confirmed that Britain and Germany had seized batches of digital versatile disc players.

the end, legal warfare was avoided and compromise was reached. In April 2002, the Chinese manufacturers reached agreements with the 6C and 3C to pay US$4 and US$5 royalties respectively for every DVD player they exported.[207] The royalty on every device using the MPEG-2 standard was US$2.5. The Chinese manufacturers have paid a total of three billion yuan (nearly 363 million US dollars) in the patent licensing fees.[208]

To strike back, China announced that a new format known as Enhanced Versatile Disc ("EVD") had been developed and approved by the State.[209] Xinhua also said that seven patents had been granted and more were still to come.[210] It is believed that EVD would be willingly adopted by domestic DVD producers as it would relieve them from paying licensing fees to the companies that hold patents to the DVD format.[211]

However, though EVD was politically heralded as a system "ending the history that core technology from VCD to DVD had been monopolized by foreign countries,"[212] problems remained: the high prices of the EVD player may hinder its acceptance by the Chinese consumers. An EVD player would cost about 2,000 yuan ($240) in comparison with about 700 yuan ($85) for a domestically produced DVD player.[213] Furthermore, it is uncertain whether EVDs will be acceptable to the international market, which has moved toward DVDs as its standard.[214]

The lessons learned from this patent row were multi-faceted. On the one hand, it was argued that China should encourage its enterprises to engage in independent innovation and apply for patents home and abroad. Official statistics indicated that the number of China's patents for inventions peaked at 6,177 in 2000, or only 5.5 percent of that of Japan and 7.2 percent that of the United States in the same year. In 2002, China applied for 2,415 patents in foreign countries, among which only 192 were awarded, fewer than those awarded to NEC, a Japanese company, by the United States in the

207. Liu Baijia, *Milestone for Video Standard*, CHINA BUSINESS WEEKLY, December 2, 2003, *available at* http://www.chinadaily.com.cn/en/doc/2003-12/02/content_287650.htm.

208. *Patent War Looming Large in China*, XINHUA NEWS AGENCY, October 08, 2003, *available at* http://www1.chinadaily.com.cn/en/doc/2003-10/08/content_269906.htm (hereinafter *Patent War*).

209. Ted Anthony, *China Declares War On DVDs*, BEIJING (AP), November 18, 2003, *available at* http://www.cbsnews.com/stories/2003/11/18/tech/main584271.shtml.

210. *See* Kang Lim, *supra* note 190.

211. *Id.*

212. Li Heng, *China Develops Enhanced Versatile Disc (EVD) System*, The People's Daily Online, July 16, 2002, *available at* http://english.peopledaily.com.cn/200207/16/eng20020716_99813.shtml.

213. *See* Anthony, *supra* note 209.

214. *Id.*

same year.[215] This situation might be partly ameliorated, some argue, if China makes efforts at raising "the awareness of intellectual property in the whole society" and improving the legal environment for the protection of the interests and rights of the patentees.[216]

However, it has been realized that the IPRs are capable of being abused. Indeed, Zhang Qin, vice director of the SIPO, proposed amending the intellectual property laws to deal with the abuse of the IPRs by overseas firms attempting to seek monopoly. As will be seen later on, the Chinese Patent Law has no provisions effectively dealing with the abuse of patent rights and other anticompetitive acts.[217]

Case 4: AIDS

The latest official statistics released by the Ministry of Health of China showed that China had 840,000 HIV carriers, including 80,000 AIDS patients at the end of 2001.[218] That figure, according to a top Chinese health official, might rocket to 10 million by 2010 at the current infection rates.[219] However, given that there was poor reporting by local health officials[220] and also given that there was a lack of information of AIDS sufferers amongst gay people,[221] it is reasonable to doubt the accuracy of the Chinese official figure.[222] According to the United Nations' estimates, up to 1.5 million people were infected with HIV in China at the end of 2001, almost double the official Chinese estimates.[223] The United Nations cautioned that if no drastic actions were immediately taken by the Chinese government, the figure could reach 20 million by 2010.[224]

The dilemma facing South Africa and other developing countries such as India and Brazil is in large part shared by China. Chinese companies developed no drugs for the treatment of AIDS and most of

215. *See Patent War*, *supra* note 208.

216. Zhang Qin, vice director of the SIPO, as quoted, *id.*

217. *Id.*

218. *China Faces Uphill Battle to Curb Fast Spread AIDS*, CHINA DAILY, November 13, 2003, *available at* http://www1.chinadaily.com.cn/en/doc/2003-11/13/content_281096.htm (hereinafter *Battle to Curb AIDS*).

219. *China Facing Tough Challenge of HIV/AIDS*, THE PEOPLE'S DAILY, December 1, 2003, *available at* http://english.peopledaily.com.cn/200312/01/eng20031201_12935.shtml.

220. Joe McDonald, *AIDS Up Sharply In China*, April 11, 2002, *available at* http://www.cbsnews.com/stories/2002/04/11/health/main505916.shtml.

221. Henry Chu, *Lonely Battle Against AIDS in China: Health: Prejudice, Ignorance Are Rife As Disease's Toll Rises*, L. A. TIMES, March 17 2002, *available at* http://www.aegis.com/news/lt/2002/LT020307.html.

222. See, e.g., *Not For General Release*, FAR EASTERN ECONOMIC REVIEW, August 15, 2002.

223. Congressional-Executive Commission on China, Annual Report 2002, *available at* http://www.cecc.gov/pages/annualRpt/2002annRptEng.pdf.

224. *Id.*

the available AIDS drugs are either protected by patents[225] or covered by government pledges of protection.[226]

In October 2002, the SDA issued permission for the first time for a domestic company to produce and sell an AIDS drug, Zidovudine (AZT), which was no longer under patent protection in China.[227] Three other AIDS drugs, namely, Didanosine (ddI), Stavudine (d4T) and Nevirapine (NVP), whose patents expired in 2001, were later added.[228] Consequently, the cost of treatment using these four drugs will be cut by up to 90%,[229] thereby making them more affordable to the AIDS sufferers. However, the problem is that the effectiveness of these drugs is in doubt.[230] More effective drugs are still under protection in China and their prohibitive prices mean that they are not an option for most Chinese AIDS patients.

China is lobbying some Western pharmaceutical giants such as GlaxoSmithKline PLC of Britain, Merck & Co. of Whitehouse Station, N.J., and Bristol-Myers Squibb Co. of New York for reductions in the prices of their drugs.[231] Some multinational companies have agreed to cut their prices by at least half. Despite the cut, for example, a year's supply of a commonly used combination of drugs known as a cocktail still costs between $2,500 and $4,000 — out of reach for most AIDS sufferers in China.[232]

Further reductions are needed and a Chinese official has warned that China may follow the lead of countries such as India and Brazil to allow local companies to make cheaper substitutes for costly imported medications and will soon "start granting licenses for local drug firms to make and sell the medicines, even though the move would violate the foreign companies' patents" if further talks with those companies are fruitless.[233]

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225. See *Battle to Curb AIDS*, *supra* note 218.

226. "Only a few AIDS drugs are protected by patents that are valid in China, but dozens of others are covered by government pledges of protection." Peter S. Goodman, *In China, AIDS Crisis is at the Mercy of Global Commerce*, THE WASHINGTON POST, December 5, 2002, *available at* http://www.globalpolicy.org/socecon/develop/aids/2002/1205china.htm.

227. *Id.*

228. *Id.*

229. *Battle to Curb AIDS*, *supra* note 218.

230. "*ddI-d4T is on US National Institutes of Health (NIH) 'not advisable' list (as of 10 Nov 2003). *As a generic, ddI is only legally available in powdered form, which is even more difficult to take. *NVP should not be used when patient has Hepatitis-B, which is a large % (10-20%) of people in China. *None of the combinations available with domestically produced drugs are on the WHO list of recommended first-line treatment regimens." *China-ARV [i.e. anti-retroviral] Access Fact Sheet*, *available at* http://www.china-aids.org/english/factsheet-ARV.htm.

231. *See* Goodman, *supra* note 226.

232. Leslie Chang, *China Cautions It May Allow Companies to Violate Patents*, THE WALL STREET JOURNAL, September 9, 2002, *available at* http://www.aegis.com/news/wsj/2002/WJ020903.html.

233. Qi Xiaoqiu, director-general of the department of disease control of the Ministry of Health, quoted, *id.*

But the overall lack of strong action on the part of the Chinese government in providing treatment to its millions of AIDS sufferers has attracted public outcry. Some believed that the Chinese leaders had been successfully convinced by American and European pharmaceutical giants, and officials lobbying on their behalf, that abrogating the promises as made by the Chinese leaders would hurt the country's reputation among investors and undermine its commitment to free trade only months after it entered the WTO.[234] As a result, "They [the Chinese leaders]'re a lot more interested in policing intellectual property than in tackling the AIDS problem. They have been dealing with IP complaints a lot longer. For the government's image abroad, it's still a better issue for them."[235] Others argued that in working with the drug industry, the Chinese leaders are making a calculation based more on economic expediency than on compassion for human lives.[236]

For the long-term solution to AIDS, vaccines may prove to be the ultimate preventative method. However, the patent issue is a source for worry. "Few pharmaceutical companies would wait until the completion of the drug development to file patent applications. They would apply during the process at the time they consider to be most appropriate, adding to the difficulties for other researchers or developers."[237] Indeed, "The serious situations now forced us to rethink the protection of patents or lives. The patients could not wait 15 years for the drug to be available, not even a single day."[238]

Experimental Use Exception and Compulsory Licensing

Having identified the adverse effect of the patent in China, this part of the discussion now concentrates on the experimental use exception and compulsory licensing in the Chinese Patent Law. We examine this with the intent to find out whether they are sufficiently legislated in order to address the above problems and if not, what areas remain for improvement.

A. Experimental Use Exception

The Chinese Patent Law provides for the experimental use exception under Article 63 (4), which exempts from infringement any person who "uses the patent concerned solely for the purposes of scientific research and experimentation." There are no further explana-

234. *See* Goodman, *supra* note 226.
235. Stan Abrams, a patent lawyer at the firm Lehman, Lee & Xu in Beijing, quoted in Goodman, *id.*
236. *See* Goodman, *supra* note 226.
237. Shao Yiming, a Chinese researcher, as quoted in *Battle to Curb AIDS*, *supra* note 218.
238. *Id.*

tions concerning the exception either in the Implementing Regulations or in the Guidelines.

In respect of the patents for biotechnology inventions, there are no court decisions concerning the experimental use exemption. This is understandable considering the relatively recent events of patents in this area. But judging from the use of the word "solely," the exception is a narrow one, restricting it to the scientific research and experimentation only.[239] This presumed "narrow" exception is out of place with the nature of the development of biotechnology in China.

Most research and experimentation in biotechnology is conducted for the purpose of commercialization. This is especially true of China, which is inclined to tailor all research and experimentation to commercial application. The present straitjacket approach of the experimental use exemption is unable to keep pace with the needs of development. In the case of the biochip, for example, most Chinese companies will face immense obstacles in their research and development as more and more patents for the genes and sequences underlying the biochip are issued in China. In the case of the patented drugs, the act of testing and manufacturing in small quantity while still in patent for submission (to the governmental regulatory body) for marketing approval so that generic drugs can be manufactured as soon as the patents expire (the so-called "Bolar exception"[240]) is put

239. Compare, e.g., Article 53 (3) of the Dutch Patent Law 1995 which provides that "the exclusive [patent] right shall not extend to acts *solely* serving for research on the patented subject-matter, including the product obtained directly as a result of using the patented process"(emphasis added). The meaning of the provision especially in respect of the added "solely" was visited in *ICI/Pharbita and Mdicopharma (Atenolol)* [1993] NJ 735; (1993) GRUR INT. 887 by the Dutch Supreme Court. The Court was of opinion that the experimental use must be strictly interpreted with a view to the added word "solely" and it cited two scenarios where the tests fall within the ambit of the experimental use; "If, and so far as, the purpose of the experiment would justify them. This would only be the case if the person conducting the experiment demonstrates and possibly proves that the experiment is of an exclusively academic nature or has a sole object which conforms to the purpose of the Patent Act, e.g. its technical improvement." *Id.* As in *Medicopharma v. ICI* [1993] NJ 735 by the Hoge Raad, it was an infringement of patent where samples of a medicinal product were made as per a patented process and provided to the assessment board by a person other than the patentee during the currency of the patent so as to enable the product to be marketed immediately after the expiry of the patent. Likewise, when an identical issue in *Generics BV v. Smith Kline & French Laboratories Ltd* ("SKF") [1997] RPC 801 was finally referred to the European Court of Justice, it was held likewise. *Id.* at 828.

240. The "Bolar exception" is also known as the "regulatory review exception" which applies to pharmaceuticals whose marketing is subject to government regulation to assure their safety or effectiveness. It permits generic drug manufacturers to conduct regulatory testing prior to the expiration of the patent on a drug product to prepare for commercial activity after the expiration of the patent. This would allow generic drugs to be placed on the market more quickly than otherwise. In the United States, such activity was ruled as infringing the patent in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F. 2d 858 (Fed. Cir. 1984). But the holding of *Roche* was almost immediately overruled legislatively by the Drug Price Competition and Patent Term Restoration Act of 1984.

outside the scope of the experimental use exception. The effect is that more patients' lives might be claimed due to the delay.

The present incorporation of the exception is the result of copying the intellectual property law from the West. Whether this transplanting of the law can be justified and effectively used to address the specific problems inherent in China remains to be seen. It is certain that the patent law was regarded as an economic tool by the Chinese leadership when it was initially adopted, but as the adverse social impact of the patent law has begun to emerge, Chinese leadership should no longer lose sight of the public interest, which the issuance of any patent is ultimately expected to serve. A broader approach toward the experimental use exemption should be put into place so as to allow the Bolar exception, which is allowed in the United States and Canada. It is also adjudicated not contravening the TRIPS Agreement by the Dispute of Settlement Body of the World Trade Organization in the case of the complaint thereof as lodged by the European Communities and their member states.[241]

B. Compulsory Licensing

Under the Chinese Patent Law, there are three grounds for the granting of compulsory licenses. First, a compulsory license may be granted where an entity has made requests to the patentee to exploit his/her patent on reasonable terms and conditions but such requests have not been granted within a reasonable period of time.[242] The requesting entity must be qualified to exploit the invention.[243] The request to be granted a compulsory license should be made to the Patent Administration Department under the State Council and such a request may be made after the expiration of three years from the date of the grant of the patent right.[244] Second, in the case of a national emergency or occurrence of any extraordinary state of affairs, or "where the public interest so requires," a compulsory license may be granted to exploit the patent.[245]

Third, in an instance in which the exploitation of a later patented invention, which involves an important technical advance of considerable economic significance, depends on the exploitation of an earlier patented invention, the later patentee may be granted a compulsory license to exploit the earlier invention upon request.[246]

241. WT/DS114/R, March 17, 2000, the World Trade Organisation, *available at* http://www.wto.org.

242. Article 48, *the Chinese Patent Law.*

243. *Id.*

244. Rule 72, *the Implementing Regulations.*

245. Article 49, *the Chinese Patent Law.*

246. Article 50, *the Chinese Patent Law.*

The later patentee must be prepared to cross-license his/her invention to the earlier patentee upon request.[247]

Other conditions also apply, namely, the license shall be non-exclusive and non-assignable;[248] and a reasonable remuneration shall be paid to the compulsory licensor and the amount shall be negotiated by both parties. In the case of failure to reach an agreement, the Patent Administration Department under the State Council shall adjudicate.[249] If dissatisfied with the decision of the adjudication, the party may institute legal proceedings in the people's court.[250] The scope and duration of the license shall be specified and the compulsory license may be terminated when the circumstances for granting the license cease to exist.[251] The compulsory license shall exist predominately for the supply of the domestic market.[252] In the case of the compulsory license for the semi-conductor technology, it shall be limited only to public non-commercial use, or to remedy a practice determined by a judicial or administrative process to be anti-competitive.[253]

Are the limited three grounds for the granting of the compulsory license adequate in addressing the above scenarios such as to combat the HIV/AIDS diseases? The obvious answer is no and more grounds are needed, and indeed justified both in comparison with other jurisdictions and in respect to the TRIPS Agreement. Brazil's 1996 Industrial Property Law permits compulsory licensing to address (1) abuse of patent rights; (2) abuse of economic power; and (3) failure by the patent holder to supply the needs of the domestic market.[254] The grounds, along with the ground provided in Article 71[255] for combating a public health crisis, were not challenged by the United States in a recent dispute between Brazil and the United States.[256] In India,

247. *Id.*
248. Article 53, *the Chinese Patent Law*.
249. Article 54, *the Chinese Patent Law*.
250. Article 55, *the Chinese Patent Law*.
251. Article 52, *the Chinese Patent Law*.
252. Rule 72, *the Implementing Regulations*.
253. *Id.*
254. Article 68 reads, "A patent shall be subject to compulsory licensing if the owner exercises his rights therein in an abusive manner or if he uses it to abuse economic power under the terms of an administrative or judicial decision." Article 68 (1) (II) reads "the following may also be grounds for compulsory licensing: marketing that does not satisfy the needs of the market."
255. Which provides that, "In cases of national emergency or of public interest, declared in a decision of the Federal Executive Power, and where the patent owner or his licensee does not satisfy such need, a temporary non-exclusive compulsory license to exploit the patent may be granted *ex officio*, without prejudice to the rights of the owner of the patent."
256. In that dispute referred to the Dispute Settlement Body of the WTO (hereinafter *DSB*), the United States challenged the "local working" requirement in the Brazilian law. Article 68 of the Brazilian Industrial Property Law provides inter alia that if the subject matter of the patent is not worked in the territory of Brazil, specifically, if the patented product is not manufactured, or the patented process is not used in Bra-

where the "reasonable requirements of the public" have not been satisfied or "the patented invention is not available to the public at a reasonable price," a compulsory license may be granted.[257] The South African patent law permits a compulsory license to be issued in the case of a public health crisis, in which case the Ministry of Health may take all measures necessary to obtain affordable drugs to alleviate the crisis. The South African Medicines Act also permits the importation and manufacture of low-cost generic drugs to address its health crisis.[258]

Carlos Correa identified several grounds for compulsory licenses, two of which may help China effectively deal with its health-sensitive problems: the addressing of the anticompetitive practices, as for example, correcting excessive prices and other abusive practices; and the governmental use, as used to provide health care for the poor.[259]

In fact, Article 40 of the TRIPS Agreement explicitly allows national legislation to take measures to prevent or control "abuse of intellectual property rights having an adverse effect on competition in the relevant market." This ground for compulsory licensing was widely adopted by national legislation. The United States, for example, granted more compulsory licenses under its antitrust law than

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zil, the patent shall be subject to compulsory licensing. Further, if a patentee chooses to exploit the patent through importation rather than "local working", then the Brazilian law allows others to import either the patented product or the product obtained from the patented process. The United States alleged that the Article discriminated against US owners of Brazilian patents who choose to import to rather than manufacture in Brazil the patented product. The United States also alleged that the Article was inconsistent with Article 27.1 and Article 28.1 of the TRIPS Agreement. *See* WT/DS199/3 9 January 2001 and WT/DS199/2 20 June 2000 and WT/DS199/1 G/L/385 IP/D/23 8 June 2000, *available at* http://www.wto.org. The Brazilian government disagreed with the US allegation and lodged its complaint concerning several discriminatory provisions in the US Patent Act to the WTO. *See Documents Submitted to WTO Dispute Settlement Body*, *available at* http://www.cptech.org/ip/health/c/brazil/MeasAffectPatProt.html. The case was subsequently withdrawn by the United States and both governments agreed to transfer their disagreement to a newly created mechanism to settle their dispute on a bilateral basis. *See U.S. and Brazil to Cooperate on HIV/AIDS and WTO Patent Dispute,* June 25, 2001, *available at* http://usinfo.state.gov/topical/econ/ipr/ipr-braziltrips.htm.

257. S.D. Ahuja, *GATT and TRIPS-The Impact on the Indian Pharmaceutical Industry*, PATENT WORLD 28 (1994).

258. The South African government proposed to use its Medicines Act to increase access to patented products for AIDS sufferers. In March 2001, 39 multinational drug companies commenced legal proceedings and attempted to overturn the Act. But a big public backlash followed and the companies dropped their case. In parallel, following the Al Qaeda attack on New York on September 11, 2001, the US government threatened to break the patent on Bayer's anti-anthrax drug Cipro and manufacture the drug itself unless Bayer drastically decreased its sale price. Bayer agreed. "This nervous reaction cast the pall of inconsistency over the campaign which US and other multi-national drug firms had been waging against South Africa." W. H. CORNISH & D. LLEWELYN, INTELLECTUAL PROPERTY: PATENTS, COPYRIGHT, TRADEMARKS AND ALLIED RIGHTS 289 (2003).

259. Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries*, 3 TUL. J. TECH & INTELL. PROP. 1, 46 (2001).

any other country. China should provide for such a ground for compulsory licensing, especially considering the dominant position of the multinational pharmaceutical companies in China and the likelihood of the abuse of that dominant power.

The TRIPS Agreement provides special rules for the compulsory license granted to government agencies or contractors, allowing the waiving of a "reasonable commercial term" on the license, so long as the patent owner is promptly notified. This ground for compulsory licensing can be flexibly adjusted by national legislations. For example, the United States restricts the right of the patent owner only to seek compensation; its right to prevent the government or government contractor from using its patent is eliminated.[260] Codification of such a ground in the Chinese Patent Law would allow the Chinese Government to take quick and effective actions to address its health problems without becoming embroiled in legal uncertainties.

In particular regard to the treatment of HIV/AIDS, many "essential drugs" as listed by the WHO are not available in China.[261] To address its present and future health crises, China should codify compulsory licensing for those drugs. As Carlos Correa pointed out, "compulsory licenses for essential drugs would not relate to a full field of technology but to a limited number of inventions which are of utmost importance for public health, and thus may be deemed as not violating TRIPS prohibition on discrimination[262] among fields of technology."[263]

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260. 28 USC §1498 (1988).

261. The WHO has included 12 ARVs (including one combination) in the WHO Model List that sets the minimum medicine needs for a basic health care system. China does not have such a list. In China as of today, only seven ARVs (including two combinations) are available locally and none of them with a paediatric formulation (when it exists). At the moment, the "WHO essential" ARVs that are not available are abacavir (ABC or Ziagen®) and lamivudine (3TC or Epivir®) from GSK, ritonavir (Norvir®) and the combination lopinavir/ritonavir (Kaletra®) from Abbott, as well as nelfinavir (Viracept®) and saquinavir (Invirase®) from Roche. *Available at* http://www.china-aids.org/english/factsheet-ARV.htm.

262. The *DSB* in the case of Canada-Patent Protection of Pharmaceutical Products has made it clear that compulsory licensing specifically linked to public health crisis *could* not have discriminatory effect under Article 27 (1) of TRIPS, even though it relates specifically to pharmaceutical patents. The *DSB* is of opinion that differential treatment does not necessarily mean discriminatory treatment: "[Discrimination] certainly extends beyond the concept of differential treatment. It is a normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantageous treatment. Discrimination may arise from explicitly different treatment, sometimes called '*de jure* discrimination,' but it may also arise from ostensibly identical treatment which, due to differences in circumstances, produces differentially disadvantageous effects, sometimes called 'de facto discrimination.'" WT/DS114/R, March 17, 2000, the World Trade Organisation, *available at* http://www.wto.org.

263. CORREA, *supra* note 259, at 47. Though most of the so-called "essential drugs" are off-patent and the high-priced drugs most useful to the treatment of AIDS are off the list of the WHO essential ARVs, given the maneuvering capacity of multi-national

The issue of public health and compulsory licensing under the TRIPS Agreement can be better understood by looking at the recent development culminating in a special declaration ("the Doha Declaration") as adopted at the Doha World Trade Organization Ministerial Conference (November 9-14, 2001).[264] The Declaration was reached pursuant to the request of some members, mainly pushed by the African Group (all the African members of the WTO), for clarification between the TRIPS Agreement and public health.[265] It is agreed in the Declaration that the TRIPS Agreement "does not and should not prevent members from taking measures to protect public health," and that "the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."[266] The Declaration underscored members' ability to use the flexibilities built into the Agreement, including compulsory licensing.[267]

The Declaration makes it clear that, "Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."[268] Though this provision did "not add anything substantively to the understanding of TRIPS," it used the expression "compulsory license" not found in the TRIPS Agreement itself, thus resulting in the creation of awareness

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pharmaceutical companies in seeking extra protection for their off-patent drugs, such a ground is still necessary in the case of China.

264. Declaration On the TRIPS Agreement and Public Health, adopted on November 14, 2001, WT/MIN(01)/DEC/2, the WTO, *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (hereinafter *the Doha Declaration*). In this Declaration, there was an outstanding issue unresolved, the so called "paragraph 6" issue, i.e., "WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement." Article 31 (f) of the TRIPS Agreement provides that products made under compulsory licensing shall be "predominantly for the supply of the domestic market," thereby limiting the amount which countries with manufacturing capacities can export when the drug is produced under compulsory licensing. Consequently, countries without manufacturing capacities would be unable to import drugs made under compulsory licensing. This issue was finally settled on August 30, 2003 with the adoption of Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Decision of the General Council of 30 August 2003), which waives the obligations under Article 31 (f) and allows any member country to export pharmaceutical products made under compulsory licensing within terms set out in the Decision. WT/L/540 September 1, 2003, the WTO, *available at* http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm. *See also Decision Removes Final Patent Obstacle to Cheap Drug Imports*, WTO News: 2003 Press Releases, Press/350, August 30, 2003 (hereinafter *Decision Removes Patent Obstacle*) and *The General Council Chairperson's Statement*, WTO News: 2003 News Items, August 30, 2003, both *available at* http://www.wto.org.

265. CARLOS M. CORREA, IMPLICATIONS OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH, HEALTH ECONOMICS AND DRUGS EDM SERIES No. 12, WHO/EDM/PAR/2002.3, June 2002, the World Health Organization.

266. Paragraph 4, *the Doha Declaration.*

267. *See Decision Removes Patent Obstacle*, *supra* note 264.

268. Paragraph 5 (b), *the Doha Declaration.*

in developing countries about the employment of such a flexibility to meet public health and other objectives.[269]

It is an unquestionable right of member States to "determine what constitutes a national emergency or other circumstances of extreme urgency."[270] It is presumed that public health crises can represent a national emergency or other circumstances, pursuant to which compulsory licenses, if provided under national law, can be granted without prior negotiation with the patent owner.[271]

Paragraph 5 (c) of the Declaration also illustrates public health crises, including "those relating to HIV/AIDS, tuberculosis, malaria and other epidemics." The exemplified cases of epidemics indicate that an emergency "may be not only a short-term problem, but a long-lasting situation," thereby implying that "specific measures to deal with an emergency may be adopted and maintained as long as the underlying situation persists, without temporal constraints."[272]

In the sense of the relationship between the TRIPS Agreement and public health, the Doha Declaration "affirms that the TRIPS Agreement should be interpreted and implemented so as to protect public health and promote access to medicines for all," thereby "demonstrating that a rules-based trading system should be compatible with public health interests."[273]

In a broad sense, the TRIPS Agreement neither establishes a uniform international law nor embodies uniform legal requirements. Rather, it gives its member states enough leeway to fine-tune to their needs specific to their respective national cultural, social and legislative situations. "In implementing the TRIPs provisions, WTO member countries may legitimately adopt regulations that ensure a balance between the minimum standards of IPR protection and the public good. Moreover, they can adopt measures which are conducive to social and economic welfare, such as those necessary to protect public health, nutrition, and the public interest in sectors of vital importance for their socio-economic and technological development."[274]

However, insofar as China is concerned, we are left with the impression that while being a developing country, it seems to have implemented in its national legislation the standard of the TRIPS Agreement as adopted by the developed countries. The flexibilities as allowed in TRIPS, and the widespread and more applicable practices as adopted in other developing countries, seemingly have been largely ignored. The dire consequence is that China cannot effectively or efficiently address its present AIDS crisis and what may be

269. *See* CORREA, *supra* note 265, at 17.
270. Paragraph 5 (c), *the Doha Declaration.*
271. As per Article 31 (b), *the TRIPS Agreement.*
272. *See* CORREA, *supra* note 265, at 18.
273. *Id.*, Foreword, at (i).
274. *Id.* at 4.

worse, all those potential problems, such as those which have arisen in the case of the DVD, will in all likelihood soon appear in other areas, including biotechnology.[275]

CONCLUSION

Historically, a patent system, developed theoretically for the encouragement of invention and innovation, was lacking in China. In recent decades, such a system was introduced to China both out of internal desire to develop its economy and through external political maneuvering. But, unfortunately, the demerits of such a system and its adverse effects on society were seemingly ignored when it was transplanted. In the West, the patenting of biotechnology inventions has become highly contentious and controversial; its adverse effects both on society and on further development of the industry have been fully overhauled with some solutions proffered. In China, it seems readily accepted, at least politically, that the strong patent protection of inventions, including those in biotechnology, is related to the further development of the industry and the promotion of the well being of society, with the Chinese patent law adopting a straitjacket approach toward the experimental use exemption and compulsory licensing scheme.

However, as discussed above, the patent has plunged many industries into deep legal squabbling, thereby effectively dampening their development. What is worse, insofar as concerns the crucial industries such as the biopharmaceutical industry, Chinese HIV/AIDS patients are, consequently, unable to receive adequate or effective treatment and the Chinese fledgling industries, such as the biochip industry, are likely to be nipped in the bud.[276]

275. Since 1999, multinationals, such as Matsushita, IBM and Nokia, have stepped up their patent rights arrangements in China in areas such as wireless telecommunications, photoelectricity, information technology and bio-engineering. Experts warned that multinationals are expected to begin waging a patent war in China against local companies in later 2003 or in 2004. See *Patent War*, supra note 208; Taiwanese rival TSMC, accusing Semiconductor Manufacturing International Co (SMIC), China's largest chip foundry, of patent infringement, filed a law suit against it in the U.S. District Court of Northern California, see *Patent Lawsuit Rankles Chinese Chipmaker*, REUTERS, December 26, 2003, *available at* http://news.com.com/2100-1006_3-5133560.html; *US-Chinese LED Patent War Breaks Out*, INQUIRER, November 4, 2002, *available at* http://www.theinquirer.net/; *LG Sues Galanz for Alleged Patent Infringement, available at* http://english.peopledaily.com.cn/200307/11/eng20030711_119992.shtml; *Sony to Sue Chinese Battery Maker, supra* note 181; Matsushita Electric Industrial, Japan's largest consumer electronics group by sales, has warned Haier, China's biggest electronics maker by sales, against patent infringement. Bayan Rahman, *Matsushita Warns China's Haier Over Patent Infringement*, FINANCIAL TIMES, October 27, 2003.

276. The reality is that most of the basic research tools and fundamental genes have been patented by the Western companies. Even the world leading gene-chip manufacturer, Affymetrix, had to abandon a diagnostic cancer microarray for the simple reason that it was unable to assemble a sufficient intellectual property package. See *Access to Medicines for Developing Countries: The Contribution of Global R&D,*

The picture for the future is gloomy. It is estimated that over 97% of the small molecules commercialized in China are copies of foreign drugs and that, "every biotech drug produced in China—-including recombinant human interferon, thymosin, erythropoietin, human insulin and granulocyte colony stimulating factor—-is copied from foreign drugs."[277] The scope for litigation is broad but the room for development may be thrown into doubt especially in an industry like biotechnology, where, as said, alternative means for the patented genes or sequences do not exist in most cases.

A catch phrase is often heard in China these days, "Now the wolf has indeed come!" This phrase describes the sudden impact that WTO membership thrusts on the country. To chart the course for the future, however, the Chinese government, in striving for economic prosperity, should keep in clear sight its broader and long-term societal needs and afford its fledgling businesses the opportunity to familiarize themselves with the transplanted foreign legislation. Otherwise it may risk losing the very objectives it seeks to achieve with the end result that the disease is cured, but the patient killed.

Focus on the Charge, ROCKEFELLER FOUNDATION, 10 October 2001, *available at* http://www.rockfound.org/documents/549/Access_to_Medicines.pdf.

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