

Intellectual Property Rights Issues in China and the United States

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I. Introduction

Intellectual property rights (IPR) protection has been the topic of many science and technology policy debates from the halls of the US Congress to the World Trade Organization, and other international forums, and the debates go on. What should be protected? To whom should such protections be granted? Who should enforce intellectual property rights protection? How ought differences in national policies be resolved? What is the appropriate balance between intellectual property rights protection and dissemination of knowledge in the public domain? The first question to address is, perhaps, why are intellectual property rights and their protection important?

Economic studies have suggested that innovation and technical progress are important components of economic growth. Robert Solow's seminal 1957 paper showed that about 80 percent of the economic growth occurring in the United States between 1909 and 1949 was due to a component other than the capital/labor ratio. In this work, he suggests that this component is technological change.¹ Other studies have led to the conclusion that technological change or progress contributes to growth in the economy.²

This relates to intellectual property and intellectual property rights protection because it is also a generally agreed among economists and legal scholars that intellectual property rights are a way of encouraging innovation. IPR allow the entity that has invested the time and effort into the research which led to the innovation to recoup the costs by conferring a legal monopoly. And, the length of that monopoly period varies depending on the type of IPR and upon the granting nation.

Intellectual property rights can be protected through a number of mechanisms including trade secrets, trademarks, copyright, and patents. Patents are particularly interesting because generally they are conferred for a limited time and are issued to protect either a product or a process that is often associated with a new industry or business sector or company. In most countries, one must file for a patent in order to have the protection it offers. When an individual has a patent for a particular technology, she has an exclusive right to that technology meaning that no other person or entity can make use of that technology without the go-ahead from the patent holder. The patent itself does not ensure the patent holder with exclusive rights; rather it enables the patent holder to bring

suit against anyone who infringes the patent by using the patented technology without permission.³

In this essay, I will discuss the patent system in both the United States and in China, with some attention to patenting of life sciences technologies. A comparison such as this is interesting on several counts including that in one instance the patent system has been in place legislatively since the late 1700's (the United States)⁴ while in the other instance, legislative action establishing the system did not occur until the mid-1980s (China).⁵ An obvious question to ask is what can China learn from the United States? I would also contend that the reverse question ought also be asked: what can the United States learn from China? As China looks to the United States, European nations, and other countries with more extensively developed economies and more mature IPR regimes, it will no doubt attempt to select and incorporate the "best" components of each. In turn, the United States might learn from Chinese IPR practices by attempting to see through that unique perspective what principles and practices might be useful modifications to its own IPR system.

In addition, as I noted in my opening paragraph, intellectual property rights and their protection are the topic of numerous science and technology discussions. In an era of increasing globalization – both in terms of economics and trade and of international scientific collaborations, how we reach workable resolutions to national differences in treating intellectual property is essential as the world business community strives toward seamless and more efficient international interactions.

I first want to discuss briefly the patent systems for both the United States and China. I will then point to topics that I believe to be current and or emerging issues in this policy area.

II. Patents in the United States

The notion of protecting intellectual property is actually imbedded in the US Constitution, which provides for the protection of creative works and invention. This is incidentally the only reference to the federal government's role in national science policy.⁶

The Congress shall have Power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries;
~ Article 1, Section 8

The United States was by no means the first nation to adopt a patent law – the first such law was established by the Republic of Venice in 1474.⁷ Prior to this the English Crown had been granting persons with a right to a monopoly to produce goods or services. The English system evolved, and it is what served as the foundation for the American system.⁸ At the time of the passage of the first US patent law in 1790, the life of a patent was 14 years. Since its enactment, the patent law has been amended a number of times,

including for increased protection longevity. For instance, the Patent Act of 1836 kept the length at 14 years but allowed for a seven-year extension to be granted. The patent law was changed again in 1860, extending the life of a patent to 17 years. The basic structure of the current US patent law was put in place with the Patent Act of 1952.⁹ Since 1995, the length of a US patent is 20 years. This change in US policy was in accordance with the end results of the Uruguay Round of trade negotiations, which led to revisions of the General Agreement on Tariffs and Trade (GATT) and to the creation of the World Trade Organization (WTO).¹⁰

US patents can be issued for a product or a process. Three different kinds of patents can be issued by the United States Patent and Trademark Office: utility patents, design patents, and plant patents. The product or process to be patented must be novel and non-obvious and must be useful (novelty, non-obviousness, and utility).¹¹

There are a number of legislative acts in place that affect intellectual property, and a number of these affect the nation's science and technology enterprise. Two that are particularly relevant to science and technology policy are the Patent and Trademark Law Amendments Act of 1980 (Bayh-Dole Act)¹² and the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act).¹³ The former allows universities and other non-profit research institutions to own intellectual property resulting from federally funded research. This has opened the way for these institutions to engage actively in licensing technologies to the commercial sector. The latter has made it easier for generic drug manufacturers to bring their products to market. Unfortunately, several provisions of the Hatch-Waxman Act, intended to be of benefit to pharmaceutical and biotech companies of brand name therapeutics, have come under scrutiny due to concerns of abuse by the brand-name manufacturers.¹⁴

III. Patents in China

What is thought of as the 'modern' Chinese Patent Law was passed in 1985. In the early part of the 20th century with the establishment of a national governance structure, the Chinese government adopted the practice of providing patent protection to inventions of Chinese nationals.¹⁵ Eleven years later, Chinese patent protection was extended to include Americans holding US patents.¹⁶ It was not until 1932 that a patent law was actually passed and put into place. This law permitted granting of patents only to Chinese nationals; it did not recognize patents of foreign inventors, even if the non-national inventors held a patent from the United States or some other foreign government.¹⁷ The adoption of intellectual property laws, including patent laws, based on the model used in the Soviet Union took hold with the creation of the People's Republic of China in 1949.¹⁸ It was during the 1970's and 1980's that Chinese leaders acknowledged the importance of fundamental property laws to a successful market economy or mixed market-socialist economy. Efforts were made to analyze patent systems around the world and draft and pass legislation establishing a modern day patent regime.¹⁹

Today, what is patented in China must meet the requirements of utility, novelty, and inventiveness (this is comparable to the non-obvious requirement in US patent law).²⁰ Things that were patentable under the 1985 Patent Law included processes and some products; it excluded chemicals, pharmaceuticals, and most agricultural products.²¹ In the 1993 amendments to the law, these products became patentable.²² In addition, the 1985 law recognized invention patents (analogous to the United States' utility patents) and utility models, a form of petty-patents recognized by a number of other countries but not the United States.²³

It is interesting to note that in ancient China as in other cultures, the notion of an individual owning and having rights over any intellectual creation was not supported. Confucianism influenced the way of thinking in ancient times putting emphasis on personal development rather than personal gain. Individual creativity was important in as so much that it contributed to society as whole. That creative and inventive achievements could be owned by an individual and protected by property rights was not just foreign to the Chinese way of thinking, but it was "essentially beyond the scope of their mental picture of the world".²⁴

IV. Policy issues

As China proceeds in developing its patent system, there are a number of policy issues to be considered.

One issue of concern that was expressed at the China-US Forum on Science and Technology Policy, October 2006 was that of *indigenous innovation*.²⁵ This is a term used by Chinese officials to describe a goal they are striving to achieve. Loosely, this term seems to refer to the notion that the China's people should become contributors and users of technologies that are developed by Chinese scientists and engineers. Some US officials and others are slightly uneasy with the use of the phrase and the prominence that the Chinese have placed on reaching the goal. This is partially due to the fact the exact meaning is literally "lost in translation". Other concerns of course are related to the United States' desire to remain the global leader in science, technology, and innovation.

With its recent admission to the World Trade Organization, China has had to be concerned with its successful implementation of WTO treaties, including the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement.²⁶ One of the goals of the TRIPS agreement was to address the issue of piracy of intellectual property. Developed countries have had concerns over the illegal copying and selling of products and processes in the international market place, i.e. a company from the developing world manufactures and sells a product that a multinational company still has on patent. This has been a huge concern for multinational pharmaceutical and biotechnology companies. The AIDS epidemic and the high cost of AIDS/HIV drugs and lack of availability of these in developing nations where AIDS/HIV prevalent is one instance in which such a scenario has played out. A mechanism the TRIPS agreement uses to resolve issues like that with AIDS/HIV drugs is compulsory licensing, which essentially means a patent

holder is forced to grant use and or manufacture of the patented technology to an outside party even before the patent expires.

On the flip side is the issue of biopiracy, “the development and patenting of material derived from resources and knowledge” taken from less developed nations “for the benefit of corporations” located in developed countries.²⁷ Biopiracy, or rather preventing biopiracy while still facilitating efforts to preserve biodiversity is another important policy issue for China. This is also called bioprospecting and largely encompasses the patenting of living organisms, including plants, and germ plasm.

Developing nations have proposed an amendment to the TRIPS Agreement that would require patent applicants to disclose the origin of biological materials and traditional knowledge included in the patent and to demonstrate they had received Prior Informed Consent from the government of the nation of origin. Along with this, patent applicants would be required to arrange for an access and benefit sharing plan of the materials and patented item with the people of the nation of origin.²⁸ The point of the amendment according to the developing nations is to prevent biopiracy. Many developed nations, including the United States, do not agree with the terms of the amendment and claim that it would not have the effect of limiting biopiracy.²⁹ China was not one of the original countries officially communicating this proposal to the WTO, but the Chinese government should have an interest in how this plays out given its role in the global economy and its wealth of natural resources and traditional practices.

One factor enabling China to be a player in the global economy is its ability to attract foreign investment. And one crucial factor for multinational companies in deciding whether to invest in a particular company is the strength of the government’s intellectual property rights protection.³⁰ Empirical evidence supports this: studies on the relationship between US foreign direct investment and patent strength demonstrate that companies limit their investments in nations with weak patent regimes.³¹ Survey studies also provide evidence that companies are reluctant to build research and development (R&D) facilities in countries with weak patent systems.³²

While there is no doubt the Chinese government has taken measures to develop and put in place a patent system, concern has been expressed about the enforcement of these laws.³³ A review conducted in early 2005 by the Office of the US Trade Representative found that infringement levels for nearly every form of intellectual property was at 90 percent or above. That same review found that foreign pharmaceutical companies (non-Chinese) lost 10-15 percent of their annual revenues in China as a result of increased drug and therapeutic counterfeiting.³⁴ In fact, some view the weak environment for intellectual property protection in China as being one thing preventing its market from being “overwhelmingly” endorsed by multinational companies.³⁵ Others, however, believe that the changes China has made to its intellectual property system in the last several years has made it one of the toughest systems in the world with prosecution of infringers by the Chinese government on the rise.³⁶ To take into account here is that enforcement of patent protection differs across regions within the country. In any case, China does have an interest in continuing to develop its system of patent protection and enforcement because

of its importance to the growth of China's domestic firms as they become more technology driven and R&D focused.

Also to be considered is that for poor, developing countries it is not necessarily the case that strong intellectual property protection is to its benefit.³⁷ For China, however, because of its growing R&D infrastructure and place in the global economy, the situation might be different. There are those, though, who argue that strong, broad patent protection is not necessarily a good thing regardless of the country. This point is argued particularly for university-based research and often in the life sciences.³⁸

In 1980 the US Congress passed the Bayh-Dole Act, and this Act is often attributed with the success of the US R&D enterprise over the past two and half decades. Because of this, other countries either have put into place or are seriously considering adopting legislation similar to the Bayh-Dole Act because of the apparent link between it, technology transfer between universities and industry, and economic growth. It has been argued, though, that growth in university-industry relations was underway before the passage of the Bayh-Dole Act and that growth in the biotechnology and information technology sectors would have occurred regardless of the Bayh-Dole Act.³⁹

The Bayh-Dole Act is the likely source of the increase in patenting of what are commonly referred to as research tools. Research tools are the technologies that are upstream in the product development process. They can be materials or processes that might be used by many other scientists in their quest for developing a particular therapeutic compound or test. Research tools might be materials or processes that are useful to basic researchers in their daily research endeavors. When a research tool is patented – protected by intellectual property rights, its use by other scientists is greatly limited and some would argue that this in turn puts restrictions and hindrances on progress in science.⁴⁰ Research tool patents can concentrate the right to use the technology in the hands of a few (some would argue that the Wisconsin Alumni Research Foundation (WARF) patents on the process of human embryonic stem cell derivation and products is an example of this) or they can create a situation in which in order for a researcher to proceed, she must license various research tools from various patent holders (some would argue that this situation is created by the patenting of DNA sequence).⁴¹

I mentioned at the beginning of this essay that there are things China, a country with a relatively young modern patent system, can learn from the United States, a country with a more established patent system. One area in particular in which I think Chinese policymakers should look to the United States experience is with the Bayh-Dole Act and the patenting of research tools. In this case, I think China might not want to follow the exact same path that the United States has taken. Whether there is any real long term social benefit from the Bayh-Dole Act and from the increased technology transfer and licensing activities of universities is not quite clear. Nor is it clear that social benefits result from the patenting of research tools in the life sciences.

Another point of criticism regarding Bayh-Dole is that it has led to increased conflicts of interest for universities and university research and that it has even decreased the

integrity of science. While people laud the Bayh-Dole Act for facilitating interactions among industrial and university scientists;⁴² others say these increased interactions have come at a cost, in particular where unfavorable findings from drug studies have been suppressed.⁴³ In addition, there is a notion that universities are becoming too engrossed in technology transfer simply as another means of generating revenues, so much so that they are being aggressive at the negotiating table with potential industrial licensees.⁴⁴

The Hatch-Waxman Act offers another point from which China might learn from the US experience. The original legislation does facilitate bringing generic versions of brand name drugs to market more quickly, but it also has provided loopholes that brand name pharmaceutical companies have used to extend the exclusivity of a brand-name drug. Examples include patenting additional features of a drug when it is about to go “off patent”, brokering deals with generic drug manufacturers that essentially result in delaying the production and marketing of a generic version, and manufacturing or authorizing the manufacture of a generic version (such that the brand name pharmaceutical company a) has a say in the pricing and b) receives some revenue from sales).⁴⁵

While the intent of the Hatch-Waxman Act was to facilitate bringing generic, more affordable drugs to market sooner, it is relevant to keep in mind the importance of patents to the pharmaceutical industry. Because of the intricate link of affordable therapeutics to affordable healthcare and overall national well-being, if China ever were to reach a point of considering something like the Hatch-Waxman Act, it might do better to find incentives for drug makers to directly provide drugs at lower costs. Since patents are important to the pharmaceutical industry – more so than in other industry, it seems that governments would do well consider mechanisms that allow pharmaceutical companies to have strong R&D programs while re-covering investments without the incredible consumer prices, e.g. subsidies and substantial tax credits.

I think if the Chinese government proceeds cautiously taking the empirical evidence into account, it has the opportunity to establish a system that can achieve the goals of stimulating innovation, inventiveness, and investment in R&D without hindering basic scientific research. In fact, the United States might find some of the practices implemented by China reasonable modifications to make to its own system.

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