Analysis on the Evolution and Governance of the Biotechnology Industry of China

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EXTENDED ABSTRACT

The past twenty years have witnessed the high-speed growth of China's biotechnology industry, and this presents an excellent opportunity to examine the changes that have taken place, especially, to carry out overall evaluation and governance analysis from the perspective of technology policies. Although China's biotechnology industry has achieved tremendous extension both in scale and structure, the strengths it gained from basic research have been significantly weakened by commercialization. This has resulted in the comparatively limited scale of the whole industry, innovation-lacking products, poor output from research and development and scarcity of industrial resources. A large range of literature regarding China's biotechnology industry attributes these outcomes to vague and even inappropriate governance, findings supported mainly by analyses based on the linear model of impact of government policies on industrial development. In these analyses, government, enterprises and companies as well as R&D organizations are either put on the opposite poles or in a straight line.

After examining the nature of China's biotechnology industry, and in particular the dynamic procedures in research and development, the authors of this paper argue that besides government, enterprises and R&D organizations, a diverse array of factors should be taken into account as we tackle issues emerging in understanding the development of China's biotechnology industry. Furthermore, these factors, human or nonhuman, should not be arranged as opposing poles or linearly connected points on a straight line. They are in fact all knitted in networks and act as both knitters and knots. China's biotechnology industry gains its strength to develop and evolve from these networks, thus its governance must be aimed at improving their stability and quality.

Although the main disciplinary perspectives of this research are historical and sociological (including identification of the three development stages of biotechnology in China since 1978 to present days), a large number of concepts and ideas from management studies as well as an interdisciplinary approach are also incorporated into the analysis.

The main model used in this research is Actor Network Theory, which is employed as a basic theoretical frame. From this starting point the authors attempt to make a closer examination of China's biotechnology industry both at the level of technology research and development and at the level of commercialization. The modeling process in this research can be regarded as an attempt to explore the social construction of China's biotechnology industry. The paper reveals how China's biotechnology industry develops in the form of networks within the country's social context and what kinds of relationships exist among the relevant factors; therefore, providing guiding insights for improving the governance of China's biotechnology industry both in policy and management.

1. INTRODUCTION

The last few decades witnessed the high-speed growth of China's biotechnology industry, which has currently become a focus of academic research not only in economics but also in a large array of other fields such as management and policy studies. Because of the strong relationships between biotechnology as an industry and as science and technology (S&T) development, China's biotechnology industry can also serve as a study objective in S&T Studies (STS). Therefore, a useful approach to examining its evolution can rise out of the sociology of S&T (Biagioli, 1999).

As the main outlet of biomedical and biotechnological research, bio-pharmacy plays the role of a knot between basic biologic research and biotechnology industry. The picture of China's biotechnology industry will be incomplete without a systematic analysis of the country's bio-pharmaceutical industry, which share in China's biotechnology industry has increased steadily in the past twenty years. Although bio-pharmacy is a subset of the total biotechnology sector, it is the main focus of the analysis here because of the growth potential it holds (other biotechnology subsets such as genetic testing, gene therapy or environmental biotechnology are less likely to become large industrial applications).

In this paper, the bio-pharmaceutical industry is taken as the key point for systematically analyzing the evolution of the biotechnology industry of China. By employing Actor Network Theory as the main theoretical frame, we attempt to explore China's biotechnology industry both at the level of technology research and development (R&D) and at the level of commercialization, in order to reveal how this industry develops in the form of networks within a social context and what kinds of relationships exist among any relevant factors thereby unknotting the problems that have emerged. The last section considers the policy implications from our findings.

2. EVOLUTION OF CHINA'S BIOTECHNOLOGY INDUSTRY

China has a long history of biomedicine, and from the age of legend, traditional forms of biotechnology have existed. It is widely believed that Shen Nong who was generally regarded as the god of agriculture, invented a transparent stomach covering in order to observe the effects of herbal medicines on the digestive tract. In the Sui Dynasty (581-618), a vaccine against smallpox was developed, and during the Ming Dynasty (1368-1644), it became widely available to the masses. Despite this early inventiveness, China's biotechnology failed to go through the explosive changes as western science did in the 17th to 19th centuries. As noted by Needham (1954), China never underwent a scientific revolution until the foundation of the People's Republic of China in 1949. Soon after that, with the "Great Leap Forward" policy (which was initially launched in 1958 in an effort to catch up with, and try to surpass, the technological development of the industrially advanced countries) Chinese scientists succeeded first in the world in synthesizing the crystalline bovine insulin on 17 September 1965, signifying a crucial step in understanding life and exploring its secrets. This discovery however did not bring the first light of morning to the development of China's modern biotechnology industry.

In the 1970s, recombinant DNA was developed to isolate and characterize deoxyribonucleic acid (DNA), which allowed scientists to work with living systems (Hara, 2003). The transfer of genetic information into living organisms provides the means to produce valuable pharmaceuticals and cure human genetic diseases. The development of biotechnology in the West was thus accelerated, however, China was still in the throes of the Cultural Revolution, and Chinese scientists had little chance to participate in the development of modern biotechnology. It was not until 1978 that China's biotechnology as well as a large array of scientific research programs were initiated in the "Spring of Sciences". The three stages in the development of China's biotechnology industry that followed are described below.

2.1 First stage: initial starting

In 1978, biotechnology was first mentioned as a focal point of China's S&T development program. Following that, it became the top priority in the high technology field (Hamer and Kung, 1989). During the Sixth 5-Year Plan (1981-1985), funds were allocated to support biotechnology research in the fields of agriculture, food processing and pharmaceutical production. From 1981 to 1985, the funding for biological research increased more than 25-fold, and new mechanisms were introduced to allocate these monies by competitive, peer-reviewed grants. In 1983, the China National Center for Biotechnology Development (CNCBD) was established to coordinate the country's biotechnological research activities.

During the Seventh 5-Year Plan (1986-1990), the level and scope of biotechnology funding also increased greatly, and around 1989, China's investment in biotechnology, as a percentage of its gross national product, was comparable to that in many western countries. In March 1986, the State Council Leading Group on S&T of China published a pivotal document and launched “The National High Technology Research and Development Program of China”, regularly referred to as the "863 Plan", which confirmed biotechnology as the top priority in China's high technology development program. That same year, the National Natural Science Foundation of China (NSFC) came into being to support biotechnology as well as other basic research. In 1988, the State Science and Technology Commission (SSTC) published the white paper on S&T, which reinforced biotechnology as China's number one priority for high technology development. These events in effect set the stage for the current mechanisms for determining biotechnology research priorities, administration and funding. In this period, the total investment in China’s biotechnology and closely related fields was approximately 100 million yuan, or 20 million yuan per year. These monies were provided through the Chinese Academy of Science (CAS) and the Ministries of Agriculture, Public Health, Medicine and Light Industry. In 1987 for instance, 108 projects out of a pool of 150 applications were approved and supported; the average grant was 200,000 yuan, and certain key projects were funded up to 2 million yuan (Hamer and Kung, 1989). The areas of research solicited and funded by the Seventh 5-Year Plan mainly focused on basic genetic engineering, plant genetic engineering, chromosome engineering, cell engineering, enzyme engineering, downstream processing and bioengineering products.

China started to show interest for a presence on international markets but the numbers of registered foreign patents were quite small. During 1978-1995, there were only 150 US patents (105 in pharmaceuticals and 92 for other biotechnology products) by Chinese nationals[1]. By the end of 1996, two new types of research centers were inaugurated in China to promote the development and commercialization of this field. Firstly, two Biotechnology Bases located respectively at Jiangmen and Shanghai, designed to bring research results to the production stage were established. Secondly, ten State Key Laboratories (summarized in Table 1) carried out most of the basic research and provided research training for scientists from throughout China.

[1] Data retrieved from the US Patent and Trademark Office.

2.2 Second stage: steady growth

During the Ninth 5-Year Plan (1996-2000), China’s biotechnology industry embraced the stage of steady growth in scale. There were 39 publicly trading biopharmaceutical firms in China by 2000, and China has co-operated with 152 countries in science and technologies and signed bilateral S&T co-operation agreements with 99 governments (Ding, 2007). During this period, the biotechnology sector enjoyed substantial scientific success and grew steadily to a considerable size. China’s ambition for a presence in the global market was demonstrated with a total of 217 (156 pharmaceutical and 177 for other biotechnology products) patents registered in USA[1].

Table 1 China’s State Key Laboratories in biotechnology

Year of Establishment	Location	Name
1984	FuDan University, Shanghai	State Key Lab of Genetic Engineering
1985	Beijing University, Beijing	State Key Lab of Natural and Biomimetic Drugs
1985	Shanghai Cancer Institute & Jiaotong University, Shanghai	State Key Laboratory of Carcinogenesis
1989	Zhong’nan University, Hu’nan	National Lab of Medical Genetics of China
1991	Nanjing University, Jiangsu	State Key Lab of Pharmaceutical Biotechnology
1991	Academy of Science, Beijing	State Key Lab of Medical molecular biology
1991	Shanghai Institute of Material Medica, Academy of Science, shanghai	State Key Lab of New Drug Research
1991	East China University of Sci & Tech, shanghai	State Key Laboratory of Bioreactor Engineering
1992	FuDan University, Shanghai	State Key Lab of Medical Neurobiology
1996	Qinghua University, Beijing	Lab of Structural Biology

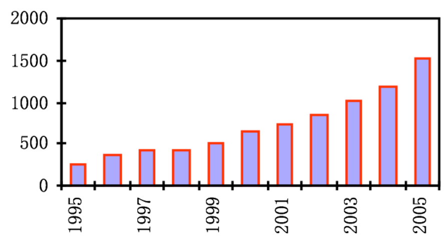

Figure 1. Value added of pharmaceutical industry in China (100 million yuan)
Source: National Bureau of Statistics et al, China Statistics Yearbook on High Technology Industry (2005).

For example, recombinant human interferon Europium αlb, the first Chinese production of genetically engineered drugs, which is also the world's first genetic engineering drugs using Chinese gene cloning and expression, was developed in 1989, and it is so far the only one with self-owned intellectual property developed independently by Chinese scientists. Following this, the bio-pharmaceuticals grew at a high speed: 12 genetic engineering pharmaceuticals came into the market of China in 1996, the proceeds of sale were 0.22 billion yuan which increased to 0.72 billion yuan in 1998 and 2.28 billion yuan in 2000 with an average annual growth rate of 79% (DHTID, 2003). In 1996, the output value of biotechnology pharmaceuticals was approximately 1.8 billion yuan with profits of 0.5 billion yuan, while a year later, their output value increased to 3 billion yuan, and at the end of 2000, this number doubled to 6.9 billion yuan. The added value of pharmaceutical industry also increased significantly (see Figure 1), and there were more than 300 enterprises producing more than 20 bio-technological pharmaceuticals in China.

Despite the progress made during the period of the Ninth 5-year Plan, China's biotechnology industry confronted a series of problems which would impede its further development. As during the first period, in the Ninth 5-year Plan biotechnology research remained funded almost entirely by the Chinese government (Wang, 2002). Although there were hundreds science-based companies and research institutes, the biotechnology sector remained largely an academic affair because of the little discovery ability and capacity in China's bio-pharmaceutical field. Few patented drugs were developed with commercial purpose. Even worse, the missed opportunities in small molecule and antibody therapy restricted the market expansion of China's bio-pharmaceutical industry in its most recent stage.

2.3 Third stage: accelerated extension

In 2001 the Chinese government started the Tenth 5-year Plan (2001-2005). Under it the development of the biotechnology industry was characterized by accelerated extension: the annual output of the Chinese fermentation industry stood at US$ 20 billion; nearly 400 thousand tons of industrial enzymes are produced every year; the bio-diesel production capacity is about 100,000 tons and China has the world-leading enzymatic technology for bio-diesel production. The annual production of methane is approximately 5.6 billion m^3, and China has become the largest producer of antibiotics, glutamic acid, citric acid and vitamin C. The number of US patents with Chinese inventors almost doubled to 414 (238 for pharmaceutical and 270 for other biotechnology products)[1]. By the end of this period, each indicator of the whole pharmaceutical industry greatly exceeded the plan: industrial output value, industrial added value and total profits more than doubled those of the Ninth 5-year Plan (Fang, 2006-7).

Apart from the expansion in industrial scale, the economic structure of China's bio-pharmaceutical industry further improved. By accelerating the organizational structure adjustment and enlarging their sizes via recombination and shareholding reforms, a number of large-scale enterprises became listed in the Shanghai and Shenzhen stock exchanges. On the other hand, many small and medium-sized enterprises (SMEs) were still confronted with shortage of intellectual property rights, low R&D expenditure and technological inferiority, which was determined by the industry's inborn high demands in technology, capital and R&D. Nevertheless, during the Tenth 5-year Plan period, especially after China joining the World Trade Organization (WTO), more and more foreign-funded enterprises surged in China's high-end bio-pharmaceutical market. While forcing the domestic bio-pharmaceutical enterprises to constantly reform and integrate so as to improve their degree of concentration and competitive ability, they would also wash out completely most SMEs. Together with the inner-industry or cross-industry merger and reorganization in bio-pharmaceuticals, the structure of China's biotechnology industry became much better balanced.

In this stage, biotechnology research and industry development in China entered a new era with the creation of a national biotechnology leadership group. Funding for biotechnology research came from two sources: government and enterprises. From 2000 to 2005, the Chinese government has in total spent about 10 billion yuan on biotechnology research mainly through the Ministry of Science and Technology (MOST), NSFC, CAS and relevant local government; among these, MOST administrated more than half of the government funding. Besides government funding, companies were estimated to invest roughly 500 million yuan. As a result from the strong emphasis on research and development, 30 types of new biotech-drugs were commercialized in this period, and over 150 biotechnology products were in clinical trials, the annual growth rate of the bio-pharmaceutical industry was more over 20%.

3. CHINA'S BIOTECHNOLOGY IN ACTOR NETWORKS

From 1996 onwards, the industrial scale and structure of China's biotechnology industry have improved tremendously, however, the past twenty years also saw the strength this industry gained from basic research significantly weaken, namely in the progression to commercialization, the comparatively limited scale of the whole industry, innovation-lacking products and poor output from R&D. It is commonly assumed that these issues were caused by somewhat vague and inappropriate governance. However after examining closer China's biotechnology industry within the model of Actor Network Theory (ANT), we argue that besides government, enterprises and R&D organizations, a diverse array of factors should also be taken into account; furthermore, the relationships among them determine the stability of the whole networks, therefore driving the development of China's biotechnology industry.

3.1 Actor Network Theory

Initially created in an attempt to examine the processes of innovation and knowledge-creation in S&T, ANT was first put forward by Michel Callon and Bruno Latour in the early 1980s (Yearley, 2005). By analyzing large scale technological developments in an even-handed manner to include political, organizational, legal, technical and scientific factors and insisting on the agency of nonhumans, ANT maps the simultaneously material and semiotic relations in heterogeneous associations of humans and nonhumans, so as to explain how material-semiotic networks come together to act as an apparently coherent whole and explore how actor networks are formed, hold themselves together or fall apart. Since 1990, ANT is widely adopted as an approach for analysis of heterogeneous relations in organizational analysis, health studies, sociology, anthropology, feminist studies, economics and so forth.

As one of the core concepts in ANT, translation serves as the basic tool for understanding the development of technology. In the course of translation, innovators attempt to create a forum, a central network in which all the actors agree that the network is worth building and defending. Four moments of translation are defined by Michel Callon (1998; en.wikipedia.org): Problematisation, Interessement, Enrolment and Mobilization. The first moment allows to get delegates representing various groups of actors identified, including the primary actor who tries to establish itself as an Obligatory Passage Point (OPP) between the other actors and the network, therefore making itself indispensable. Interessement makes the actors interested and negotiate the terms of their involvement. The primary actor now works to convince the other actors that the roles it has defined for them are acceptable. During Enrolment the actors accept the roles that have been identified for them, which results in the enrolment of all relevant human and nonhuman factors as Actants. The last moment, Mobilization, ensures the enrolment is actively supported, and the delegate actors adequately represent the masses.

Holding the rationale that differences between human and nonhuman actors are generated in the network of relations, it should not be presupposed, ANT argues that all the elements in a network, human and nonhuman, can and should be described in the same terms. This is called the principle of generalized symmetry. Furthermore, it talks of Actants to denote human and nonhuman actors, and assumes that the actors in a network take the shape that they do by virtue of their relations with one another. It assumes that nothing lies outside the network, and suggests that there is no difference in the ability of technology, humans, animals or other nonhumans to act. The ANT model notes that as soon as an actor engages with an actor network it too is caught up in the web of relations and becomes part of the entelechy.

3.2 Actor Networks of China's biotechnology industry

The set of reforms have set China's biotechnology industry on a solid footing as an innovation system, through the reorganization of R&D organizations and the promotion of heterogeneous relationships among various actors embedded in the social context. Nevertheless, the networks of the Chinese biotechnology industry are still confronted with instability, which in the large extent causes biotechnological products to be hard to move from the laboratory to the market. The excellence in science as well as the expertise available in universities and public research institutions are far from being exploited to their full potential.

From the initial stage of development, the Chinese government has retained the position of OPP between actors and networks in the biotechnology industry. Evidence of this is the mainly government funded biology research and industrial development (see Table 2). Through the national system of administration, the Chinese government strengthens the linkage between the enrolled actors after getting delegates representing the groups of actors identified, so as to enable the actors to negotiate the terms of their involvement while holding that their roles assigned by government were acceptable. By mobilization, the networks of China's biotechnology industry became widely supported, and the delegate actors adequately represented the masses. Therefore, the interests of different human and nonhuman actors were translated into the interests of the whole networks.

In the R&D section of biotechnology, networks made by human actors, mainly scientists, funding bodies and administrative staff, and nonhuman actors (facilities, research money, plants, animals and so forth) were linked by programs. These programs were initiated by the Chinese government to launch the translation of interests. During the moments of translation, the formation and stability of networks were ensured by funding and administration mainly from MOST (which conducted 973, 863, Torch, and Special Programs), NSFC (which focused on basic research), National Development and Reform Commission (NDRC) responsible for industry development and industrial policy, the State Food and Drug Administration (SFDA), CAS supporting related institutes, and Ministry of Education (MOE) supporting related universities. Among them, the Bureau of Life Science and Biotechnology affiliated with the Chinese Academy of Science demonstrated well the OPP position the Chinese government has set for itself in the networks. With 21 research institutes, 3 biotech research bases (Shanghai, Beijing, West-South China), over 6000 R&D personnel, 7 focused research area, 2 Priority development areas (Biotechnology and Pharmacy), the Bureau created a token of China's biotechnology R&D in the form of network.

Table 2 R&D by source of funds and sector of performance, 2004 (billion yuan)

	Performance sectors				
Source of funding	Research institutes	Enterprises	Universities	Others	**Total**
Government	344.3	62.6	108.8	7.8	523.6
Enterprises	22.4	1189.3	74.5	5.1	1291.3
Abroad	2.6	19.8	2.6	0.1	25.2
Others	62.4	42.3	14.9	6.6	126.2
Total	431.7	1314.0	200.9	19.7	1966.3

Source: Annual S&T report, MOST 2005

The successful formation and consolidation of networks guaranteed the accelerated development of China's biotechnology industry. China's participation as the only developing country in the Human Genome Project (HGP) and Chinese researchers successfully sequencing 1% of the human genome with an accuracy rate of 99%, showcased the country's capability in biotechnological research (Breithaupt, 2003). Nevertheless, both the quality and stability of China's biotechnology industry networks need to be improved. There are currently approximately 500 bio-pharmaceutical companies in China with annual sale proceeds of about 34 billion yuan, however, the share it occupies in the whole pharmaceutical market is less than 10%. The lack of group-scale enterprises, poor competitive power, innovation-lacking products, pressure from foreign-owned enterprises' entering and further limitations are weakening the strength of China's biotechnology industry networks.

4. CONCLUSION: POLICY IMPLICATIONS

Biotechnology continues to be the top priority for China's 2006-2020 S&T Development Plan (Ding, 2007). Despite the rapid growth achieved in the past twenty years, China's biotechnology industry still has a large range of restricting actors which severely threaten the whole networks. Among these actors, limited funding, low investment, insufficient research personnel and domestic collaboration are ranked at the top of the list.

The shortage of financing options creates the first major bottleneck for the Chinese biotechnology industry. The government remains the main source of funding for R&D and commercialization. Besides, China's biotechnology enterprises also find it particularly difficult to attract investment because of the short-term expectations of the Chinese investor community. Investors in China are focused on returns on investment that can be received more rapidly than what is typical for health biotechnology ventures, renowned for their risky nature and protracted development times. As a result, Chinese companies have steered away from high-risk, capital-intensive R&D activity and toward commercialization of more mature and less risky technologies such as in generic manufacture (see Figure 2).

Insufficient research personnel and domestic collaboration resulting from the scattered industrial structure are also challenging the stability of China's biotechnology industry (see Table 3). Even worse, according to a Ministry of Personnel (MOP)'s estimation, about 580,000 Chinese students have left the country to study since the late 1970s, with only about 160,000 returning (Li et al., 2004). Of the nearly 300,000 Chinese students overseas at present, one-third are involved in the biotechnology field. This seriously limits the source of research personnel supply. On the other hand, although universities and public research institutions are capable of conducting world-class research, their activities are not connected to the budding industrial sector. Patent statistics reveal that public research institutes and universities own 80% of all biotechnology patents, but only 6% of new biotechnology therapeutics and vaccines in China are the result of joint developments by universities and enterprises (Liu, 2006).

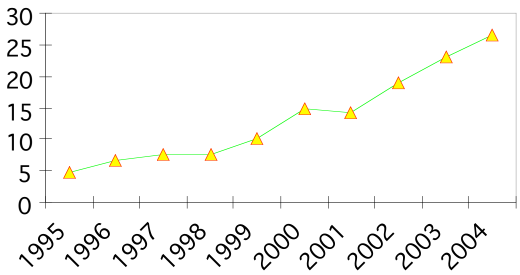

Figure 2. Expenditure for new products of pharmaceutical industry (100 million yuan)
Source: National Bureau of Statistics et al, China Statistics Yearbook on High Technology Industry (2004).

Table 3 Biotechnology industry by country

Item	China	India	USA	Germany
Bio-tech Company	>500	240	1460	365
Personnel	50,000	25,000	140,000	14,000
Laboratory	400	—	500	—
R&D Personnel	20,000	—	—	—
Bio-tech park	20	—	5 bio-tech zone	—

Source: Bio-industry in China annual report 2005

Along with the growing foreign-capital investment and rapid reforms and reorganization among domestic enterprises, we argue, it is an advantage for domestic biotechnology enterprises to establish a sound competitive cooperation. Furthermore, several large-scale groups should be established via strategic alliances such as mergers and acquisitions. In this way, market expansion and enhancement of strength can be achieved with an enlarging enterprise scale and trade value. To overcome the barrier of limited funding and low investment, the Chinese government needs to take measures such as simplifying foreign investment procedures, protecting the natural environment and improving infrastructure so as to make the investment environment more attractive. It is even more important to construct an industrial culture within the networks of China's biotechnology industry. Cultural differences between foreign investors and Chinese staff can delay the enrollment of foreign investment to the actor networks of China, and cultural differences between nations cannot be removed within a short time; the industrial culture thus becomes crucial.

To deal with the insufficiency of research personnel and domestic collaboration, we argue, a national system of innovation should be set. Taking its advanced capability in genomics/ genetics research, the networks of China's biotechnology industry can translate their interests into that of the innovation system which is promising in creating the waves of returnees from overseas (Wong, 2006), also in the networks of larger scale effectiveness of the overall operation of highly talented and skilled scientists.

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